

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Richmond Division

ALFREDO R. PRIETO

v.

HAROLD W. CLARKE, EDDIE
PEARSON, DAVID ZOOK, and
OTHER UNKNOWN EXECUTIONERS,
EMPLOYEES, AND AGENTS

Civil Action No.
3:15 CV 587

October 1, 2015

**COMPLETE TRANSCRIPT OF MOTIONS
BEFORE THE HONORABLE HENRY E. HUDSON
UNITED STATES DISTRICT COURT JUDGE**

APPEARANCES:

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Robert E. Lee, Jr., Esquire
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OFFICIAL COURT REPORTER
UNITED STATES DISTRICT COURT

E X A M I N A T I O N S

	DIRECT	CROSS	REDIRECT	RECROSS
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Dr. James Ruble	20	50	55	--
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Arnold Robinson	62	75	78	--
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Carlos Hernandez	79	85	--	--
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(The proceeding commenced at 1:01 p.m.)

THE COURT: Good afternoon.

All right, Ms. Pizzini, call our next case, please.

THE CLERK: Number 15 CV 587. *Alfredo R. Prieto v. Harold W. Clark, et al.*

The plaintiff is represented by Ms. Elizabeth Peiffer and Mr. Robert Lee, Jr.

The defendants are represented by Ms. Margaret O'Shea and Mr. Richard Vorhis.

Are counsel ready to proceed?

MS. O'SHEA: Yes, Your Honor.

MS. PEIFFER: We are, Your Honor.

THE COURT: This matter is before the Court this afternoon on an emergency petition seeking preliminary injunctive relief, essentially seeking to enjoin the execution protocol contemplated by the Commonwealth of Virginia in this case. It is based upon an alleged Eighth Amendment violation, and it is to be reviewed on an as applied basis, as I read the petition.

On that preface, I will go ahead and hear any opening statements you may have. I will take any evidence you would choose to present, then I'll hear closing arguments, and I will issue an opinion this afternoon, all right? Very well.

Ms. Peiffer.

1 MS. PEIFFER: Good afternoon, Judge.

2 THE COURT: Good afternoon, ma'am.

3 MS. PEIFFER: We are here today, and we have
4 requested that the defendants be enjoined from executing
5 Mr. Prieto this evening at 9:00 at Greenville
6 Correctional Center, using a compounded substance
7 purported to be pentobarbital, until the Virginia
8 Department of Corrections can provide evidence
9 establishing that the exercised due diligence in
10 acquiring, and analyzing, the information needed to assess
11 risk.

12 We ask the Court that they allow the temporary
13 restraining order granted yesterday by Judge Trenga to
14 remain in effect, and allow discovery, and an opportunity,
15 to ensure that the execution of Mr. Prieto would not
16 violate the Eighth Amendment.

17 We do not seek to interfere with the Commonwealth's
18 ability to execute someone in a manner consistent with the
19 Constitution. That is not why we are here today. We are
20 here to discuss the specifics, and this recently obtained
21 information that the Commonwealth will be using a
22 substance purported to be pentobarbital obtained from the
23 Texas Department of Criminal Justice at the end of August.

24 We think that there's a likelihood of success on the
25 merits that there is a substantial risk of harm because

1 the Department of Corrections has recklessly planned to
2 use a drug without investigation, and that there will be a
3 substantial risk that Mr. Prieto will not be unconscious
4 or insensate for the administration of the second two
5 drugs of the lethal injection protocol. As Your Honor is
6 familiar with, the second two drugs of the lethal
7 injection protocol are rocuronium bromide and potassium
8 chloride.

9 In *Baze v. Rees*, the United States Supreme Court
10 found that if a person were not unconscious and unfeeling
11 by the time the second two drugs were administered, that
12 there would be a substantial, constitutionally
13 unacceptable risk of suffocation from the administration
14 of the rocuronium bromide and pain from the injection of
15 the potassium chloride.

16 It's for this reason that in Virginia, especially,
17 using this 3-drug protocol, the first drug, this purported
18 pentobarbital that has been compounded in this unknown
19 pharmacy, is so significant. If the first drug does not
20 work, the lethal injection protocol in Virginia will be
21 unconstitutional.

22 We have come here today with evidence, and we've
23 presented in our pleadings, some of the reasons and
24 allegations that we think that there's a problem with
25 using this substance purported to be pentobarbital. And

1 the issue is that the defendants didn't investigate. And
2 we're not saying that it would be impossible to use
3 pentobarbital --

4 THE COURT: Now, they contend in their pleading, and
5 I know the evidence will either bear this out or refute
6 it, that the Texas Department of Corrections performed an
7 independent test, and provided a copy of that
8 certification to the Virginia Department of Corrections.
9 Will their evidence not show that, Ms. Peiffer?

10 MS. PEIFFER: That is correct. We received yesterday
11 afternoon the first -- for the first time, evidence that
12 they performed some testing on April 24, 2015, before the
13 drugs were transferred to Virginia.

14 Based on the Department of Corrections' pleadings,
15 the drugs were transferred in August of 2015. And if
16 you'd like, I can speak to the laboratory report for a
17 moment that we just received yesterday.

18 THE COURT: Well, I'll hear your final argument after
19 hearing all the evidence. But when you say that they took
20 no efforts whatsoever to verify the effectiveness of the
21 drug, I just merely had to see whether or not my
22 understanding was correct that in fact they did have an
23 independent examination by a laboratory in Texas.

24 MS. PEIFFER: I'm sorry. You are correct, Your
25 Honor. There was an examination for the reasons that we

1 have presented in our pleading.

2 THE COURT: And they found it to be 94.9% pure,
3 right?

4 MS. PEIFFER: On April of 2015, it was 94.6% pure.

5 THE COURT: Okay.

6 MS. PEIFFER: I think there are two issues with the
7 testing. And we can present expert testimony on this
8 matter.

9 THE COURT: Okay.

10 MS. PEIFFER: First, is that you will notice from the
11 lab report presented as Exhibit 1, that the only testing
12 that they seem to have done was potency testing. The
13 sterility testing, which is at the top of the report, is
14 all left blank. There are three sterility tests that were
15 not performed. And this is atypical.

16 Sterility is a big issue in compounded drugs. In
17 addition, sterility is needed to give a drug, a high-risk
18 sterile injectable, such as pentobarbital. Sterility
19 testing is required if it's going to have a beyond use
20 date beyond three days. Three days is the accepted beyond
21 use date if the substance, a high-risk injectable, is
22 refrigerated. If there is not sterility testing, three
23 days is the beyond use date.

24 In this case, based on the photographs we received,
25 the beyond use date is one year, which indicates that

1 either the Virginia Department of Corrections did not
2 obtain and investigate this testing, that they still have
3 not produced all of the testing, or that they don't
4 understand what is significant in determining whether
5 pentobarbital, or the substance purported to be
6 pentobarbital, would be effective.

7 And that's really one of the issues with compounded
8 drugs, and one of the distinctions we think that is
9 important to make. Compounded pentobarbital, or the
10 substance purported to be compounded pentobarbital, is
11 very distinct from pentobarbital that is manufactured as a
12 pharmaceutical. Pharmaceuticals are regulated by the
13 F.D.A., and there are very strict regulations about
14 quality control.

15 Compounded substances are not regulated by the F.D.A.
16 They're mixed up in small batches, they are mixed up in
17 independent pharmacies, and the batch variability
18 completely determines how the drug will work. So one
19 batch mixed up in a pharmacy of 24 vials could have one
20 set of qualifications and potency and sterility, a batch
21 mixed in the same pharmacy the next day could have
22 completely different characteristics because of the way
23 compounded drugs work. So I think it's important to
24 recognize this distinction.

25 THE COURT: Ms. Peiffer, no Court has ever held that

1 a person in the situation of your client is entitled to
2 optimum sterility or optimum compounding or preparation of
3 the drug. Only to a drug that doesn't create severe pain.

4 MS. PEIFFER: That's correct. And what we are
5 alleging is that use of this drug would create a
6 substantial risk of serious pain.

7 THE COURT: Okay. All right.

8 MS. PEIFFER: There are a number of issues like I
9 just discussed with the sterility, and reasons to believe
10 that the drug might not be good. There are also issues
11 with the potency. As you remarked, the potency in April,
12 which was almost six months ago, approximately five to six
13 months ago, was 94.6%. The range of potency that is
14 acceptable for this drug is 92% to 108%. And potency
15 declines with time.

16 So this drug was manufactured -- I'm sorry. It was
17 not manufactured. It's a compounded substance. It was
18 mixed. There's a difference.

19 It was mixed almost six months ago. And potency
20 degrades with time, which means that changes the way the
21 drug works. Now, we don't know what the potency is today.
22 We can allege, and we believe, that there is reason to
23 think that it would have declined since that point.

24 Another factor that's very important to consider in
25 this particular case is that the conditions that these

1 fragile mixtures are kept in are very significant, and can
2 substantially change the way that the drug works. So
3 transporting the drug from Texas to Virginia could well
4 have changed the potency of the drug. And from the
5 information that we have received, which we believe to be
6 the only information that exists, no potency testing has
7 been done since the drug was manufactured in April in
8 Texas and moved to Virginia.

9 And so those are just some of the risks that we think
10 that the Department has taken, and some of the issues that
11 they do not seem to understand about why, in Virginia
12 particularly, this compounded substance could indeed
13 create a substantial risk of serious harm to Mr. Prieto.

14 I think another important thing to note is that
15 Virginia is fairly unique among the states that's been
16 using this compounded pentobarbital, or something -- other
17 batches of compounded pentobarbital in executions, because
18 Virginia does have a 3-drug protocol.

19 THE COURT: Has a what?

20 MS. PEIFFER: A 3-drug protocol.

21 THE COURT: A 3-drug protocol. Okay.

22 MS. PEIFFER: In Texas, where the drugs are obtained,
23 and where they've been compounding drugs, and using
24 compounded drugs purported to be pentobarbital for at
25 least two years, as far as we know, that's a 1-drug

1 protocol. So that's a very, very different kind of risk.

2 If Texas uses a 1-drug protocol, compounded
3 pentobarbital, and something goes wrong, they could give
4 the inmate more pentobarbital, or they could stop the
5 execution. They would realize that the inmate is having
6 some kind of issue.

7 In Virginia, the second two drugs -- the second drug
8 would paralyze the inmate, so there may well be no way to
9 even tell what is happening because he would be paralyzed
10 after the administration of the second drug.

11 As you may recall from previous cases, there's been
12 testimony from the Department of Corrections that the
13 lethal injection protocol in Virginia can be as quick as
14 two to four minutes. So it moves very quickly and it's
15 difficult to tell, because of the paralytic as the second
16 drug, what is actually happening with the inmate.

17 However, as the Supreme Court found, an inmate could
18 indeed experience significant risk of pain, and this would
19 violate the Eighth Amendment.

20 THE COURT: Ms. Peiffer, will your evidence show that
21 an alternative source or alternative methodology, which is
22 one of the things a lot of courts have looked to, will
23 your evidence show that pentobarbital is fairly reasonably
24 available here in Virginia at that level so that the
25 Department of Corrections could go to a different source?

1 MS. PEIFFER: An answer to a slightly different
2 question --

3 THE COURT: No. No. I want -- this is my question.
4 Is pentobarbital available to the Department of
5 Corrections in Virginia from an alternative source?

6 MS. PEIFFER: To my knowledge it is not, but that is
7 not something I have investigated.

8 THE COURT: Okay. That's a fair answer.

9 MS. PEIFFER: We have pled that there are reasonable
10 alternatives. And in fact, I think one of the things that
11 we really want to highlight today is that it could be that
12 these drugs are suitable. We are not saying that the
13 Department of Corrections in Virginia could never use
14 compounded pentobarbital.

15 THE COURT: But haven't Federal Courts around the
16 country admonished litigants that they're not allowed to
17 supervise the execution process? That that really resides
18 in the hands of government officials entrusted by the
19 people of the State?

20 MS. PEIFFER: I don't consider this supervising the
21 execution process, Your Honor. All that we're saying is
22 that this drug needs to be properly --

23 THE COURT: Well, it's a fairly granular examination
24 here.

25 MS. PEIFFER: I'm sorry?

1 THE COURT: It's a fairly granular examination that
2 you want to conduct. You admit that.

3 MS. PEIFFER: Well, there are a lot of -- there is a
4 lot of information that is significant here.

5 THE COURT: All right.

6 MS. PEIFFER: But part of the reason that we're
7 concerned is because, from the evidence, the Virginia
8 Department of Corrections is -- has not performed the type
9 of investigation that is necessary.

10 THE COURT: Okay.

11 MS. PEIFFER: If we had made this request that we
12 made it very shortly after we found out that they were
13 going to use this compounded substance, if they had been
14 able to respond appropriately, we would not be here today.
15 If they had advised Mr. Prieto that this is what was going
16 to be happening, that they were switching from midazolam
17 to compounded pentobarbital, we would have been able to
18 investigate this much sooner.

19 Mr. Prieto did not receive notice of this change
20 until the night of September 22nd. As soon as
21 practicable, we wrote a letter to the defendants asking a
22 series of questions. And that's one of the exhibits. And
23 asking for some information about the type of testing
24 because there is this concern. And we received an answer
25 the night of the 29th.

1 And frankly, Your Honor, that answer just really
2 didn't alleviate our concerns. It made them worse because
3 it indicated that there's not an understanding about what
4 compounded pentobarbital is, how it's different from
5 manufactured pentobarbital, and why that's a risk.

6 If those documents had been produced as we asked, and
7 they had showed that there was sterility testing, and they
8 had showed that the potency was tested, and there was
9 reason to believe that this drug works the same as
10 manufactured pentobarbital, that would be a feasible
11 alternative. We are not saying that there are no
12 circumstances under which the Department of Corrections
13 could use compounded pentobarbital. That's absolutely not
14 what we're saying.

15 So we have suggested that there are other feasible
16 alternatives in addition -- in the material that we filed
17 today in response to the motion to dismiss filed
18 yesterday. We suggested that another alternative would be
19 to use a 1-drug protocol because the risk here is very
20 significant because, in part, Virginia uses a 3-drug
21 protocol. So there are a number of alternatives we
22 suggested, and the alternative doesn't have to be
23 manufactured pentobarbital.

24 THE COURT: Okay.

25 MS. PEIFFER: I hope that answered your question.

1 THE COURT: Thank you very much. Yes, ma'am.

2 MS. PEIFFER: Did you have a need for further
3 questions?

4 THE COURT: Not at this point. After I hear the
5 evidence, I very well may. Thank you.

6 MS. PEIFFER: Thank you.

7 THE COURT: Ms. O'Shea, opening statement?

8 MS. O'SHEA: Yes, Your Honor.

9 Preliminary injunctive relief is a very serious
10 remedy that's asked -- that the plaintiff has asked this
11 Court to issue. It's not to be taken lightly. They're
12 not entitled to it as a matter of right simply because
13 they filed this Section 1983 suit. Issuing preliminary
14 injunctive relief of a stay of execution is an
15 extraordinary remedy, and it's not warranted under the
16 facts of this particular case.

17 The plaintiff's allegations are based on suppositions
18 and speculation, which are insufficient to satisfy the
19 standard of proof required to show an Eighth Amendment
20 claim, which is that there's a serious and substantial
21 risk of injury. There is no serious and substantial risk
22 of injury in this particular case. Pentobarbital, under
23 Virginia's execution protocol, is not used as the lethal
24 agent. It is used as a sedative.

25 Virginia has built sufficient safeguards into their

1 actual execution protocol to ensure that if the sedative
2 is not working, we will know about it. In addition to
3 that, the Department of Corrections made reasonable
4 inquiry when they contacted Texas to request the
5 pentobarbital. The Virginia Department of Corrections
6 ensured that the pentobarbital is transported in a safe
7 and secure manner. And we will present testimony on that
8 to the Court today.

9 And so for that reason, the plaintiff is not going to
10 be able to show that there's a substantial risk of serious
11 injury, and as such, he doesn't have a likelihood of
12 prevailing on the merits of this action.

13 They also do not have a likelihood of prevailing on
14 the merits of this action because they are not able to
15 proffer to the Court an available, an alternative, method
16 of execution. The alternative that they have proposed is
17 basically do more testing than what you've already got.
18 That's not a different protocol. That's just attempting
19 to slap the Department of Corrections with a
20 constitutional requirement that simply does not exist.

21 Every single Federal Court of Appeals that has
22 addressed this particular issue, the Fifth Circuit, the
23 Eighth Circuit, the Eleventh Circuit, has said that the
24 suppositions put forward by inmates who challenge
25 compounded pentobarbital are simply insufficient to save

1 an Eighth Amendment claim.

2 In addition, the plaintiff has now exhausted his
3 administrative remedies, and that is a secondary reason
4 why there's no likelihood of success on the merits.

5 THE COURT: I think you concede, it's a little late
6 at this point to pursue administrative remedies.

7 MS. O'SHEA: Well, it is. But 42 U.S.C. 1997e(a)
8 requires it. It's mandatory.

9 THE COURT: All right.

10 MS. O'SHEA: That you have to do it. And he didn't.

11 THE COURT: All right.

12 MS. O'SHEA: And the Supreme Court has said that
13 applies in lethal injection protocols, too.

14 THE COURT: All right.

15 MS. O'SHEA: If he found out on the 22nd that he was
16 going to be executed with compounded pentobarbital, as
17 they have posited, you can start the grievance process
18 right then. He didn't.

19 THE COURT: All right.

20 MS. O'SHEA: So, Your Honor, the balance of the
21 equity is irreparable harm. In the end, this all falls
22 out against issuing extraordinary remedy and preliminary
23 injunctive relief, against issuing a stay of execution of
24 this man who has been waiting for 27 years since his
25 crimes to be executed, and we're going to ask the Court to

1 vacate the ex parte temporary restraining order that was
2 issued yesterday, and deny their request for preliminary
3 injunctive relief.

4 THE COURT: Thank you, Ms. O'Shea.

5 Ms. Peiffer or Mr. Lee, go ahead and present your
6 evidence.

7 MS. PEIFFER: Yes, Your Honor. Our witness has to be
8 reached by telephone.

9 THE COURT: I can't hear you. I'm sorry.

10 MS. PEIFFER: I apologize.

11 THE COURT: No. It's okay.

12 MS. PEIFFER: We have one expert witness, Your Honor.
13 And he is in the State of Utah.

14 THE COURT: That's fine.

15 MS. PEIFFER: So he has to be reached by telephone.
16 We have made arrangements.

17 THE COURT: We can do that. What I want you to do
18 though is because my court reporter is going to take this
19 down, I want to make sure that it is sufficiently audible
20 that she can hear it, and that you speak slowly, as well
21 as your expert, okay?

22 MS. PEIFFER: Yes.

23 THE COURT: All right. Very well.

24 On that note, go right ahead.

25 MR. LEE: Your Honor, should we recess to set that

1 up?

2 THE COURT: Do you need a short recess?

3 THE CLERK: Your Honor, no. I just need to dial the
4 number.

5 THE COURT: I think we're ready, Mr. Lee.

6 THE CLERK: Could I get counsel to confirm that
7 number, Your Honor?

8 THE COURT: Yes.

9 Mr. Lee or Ms. Peiffer, come up to the Clerk's desk
10 and confirm the phone number before she calls.

11 MS. PEIFFER: Sure.

12 THE COURT: What is this witness's name, Ms. Peiffer?

13 MS. PEIFFER: James Ruble.

14 THE COURT: Could you spell that last name for my
15 court reporter.

16 MS. PEIFFER: Yes. R-U-B, as in boy, L-E.

17 THE COURT: Mr. Ruble?

18 DR. RUBLE: Yes, sir.

19 THE COURT: This is Henry Hudson. I'm the United
20 States District Judge trying this case.

21 DR. RUBLE: Yes, Your Honor.

22 THE COURT: Before your counsel asks you questions,
23 my courtroom deputy clerk, Ms. Pizzini, is going to
24 administer the oath.

25 Ms. Pizzini, go right ahead.

DIRECT EXAMINATION OF DR. RUBLE

20

1 THE CLERK: You do solemnly swear that the testimony
2 which you are about to give, in this case, before this
3 Court, shall be the truth, the whole truth, and nothing
4 but the truth, so help you God?

5 DR. RUBLE: I swear.

6 THE CLERK: Thank you.

7 THE COURT: Go right ahead.

8 Whereupon, **Dr. James H. Ruble**, having been
9 duly sworn in, testifies as follows:

10 DIRECT EXAMINATION

11 BY MS. PEIFFER:

12 Q Dr. Ruble, can you hear me okay?

13 A I can hear you. Yes, ma'am.

14 Q Okay. Good afternoon.

15 A Good afternoon.

16 Q I would like to start by just having you introduce
17 yourself to the Court, and briefly describe your
18 credentials to opine on these matters.

19 A My name is James Hoffman Ruble. My current
20 employment is as a associate professor in the clinical
21 ranks at the University of Utah, College of Pharmacy,
22 located in Salt Lake City, Utah. I've been an instructor
23 here in a full-time capacity for the past five and a half
24 years. And prior to that, I taught in an adjunct capacity
25 for more than 20 years.

DIRECT EXAMINATION OF DR. RUBLE

21

1 I've been a registered pharmacist in the State of
2 Utah since 1992. And I have experience in a variety of
3 areas in pharmacy practice. And a fair number of those
4 years have been spent in both sterile compounding
5 activities, professional activities, as well as in
6 nonsterile compounding activities.

7 In my current role as an instructor and educator, I
8 teach pharmacy students. And I teach pharmaceutical
9 science to graduate students in the areas of compounding,
10 I teach in pharmacy law, and I teach in medical ethics.
11 And in a hand full of other courses, I provide additional
12 instruction. Those are the three primary areas though.

13 I've worked in a number of major academic medical
14 centers, including the University of Utah, Health Care
15 System, located in Salt Lake City. I've worked for
16 Primary Children's Medical Center, a pediatric
17 institution, located in Utah. I've worked for an adult
18 and pediatric institution located in Pennsylvania. And in
19 a number of other community pharmacy areas.

20 I was a manager of a home infusion pharmacy, also in
21 connection with the University of Utah. We did sterile
22 compounding activities. A lot of that work was for
23 patients residing in an ambulatory environment in their
24 home or in hospice settings, or otherwise.

25 So there are a number of other qualifications I could

DIRECT EXAMINATION OF DR. RUBLE

22

1 go into, but I think as long as I have, you know, more
2 than 20 years of experience as a pharmacy practitioner
3 licensed, and a lot of that time spent in direct
4 compounding activities --

5 THE COURT: Go right ahead.

6 MS. PEIFFER: And so I would move that Dr. Ruble be
7 considered as an expert in the compounding matter.

8 THE COURT: Ms. O'Shea, is there any challenge to his
9 credentials?

10 MS. O'SHEA: Not to his credentials as a -- as a
11 pharmacist. But with respect to tying that to
12 compounding, I don't think that we have heard any
13 particular --

14 THE COURT: He mentioned that his experience did
15 involve compounding pharmaceuticals.

16 MS. O'SHEA: Okay.

17 THE COURT: He will be received as an expert, and
18 permitted to give expert testimony in the area of
19 pharmaceuticals. Is that what you're seeking?

20 MS. PEIFFER: Compounding, Your Honor.

21 THE COURT: Compounding. Yes, ma'am. He'll be
22 received in that limited area.

23 Go right ahead.

24 MS. PEIFFER: Thank you.

25 BY MS. PEIFFER:

DIRECT EXAMINATION OF DR. RUBLE

23

1 Q Dr. Ruble, did you have occasion to speak with me,
2 Elizabeth Peiffer, and Robert Lee on some occasion
3 approximately a week ago?

4 A Yes, ma'am.

5 Q And did we ask you to review certain records?

6 A Yes, ma'am. I have reviewed a couple of different
7 documents that you provided to me.

8 Q And did some of those documents involve information
9 about compounded pentobarbital in the possession of the
10 Virginia Department of Corrections?

11 A Yes, ma'am, they did.

12 Q Can you just briefly describe for the Court the
13 documents that you reviewed concerning this compounded
14 substance?

15 THE COURT: Yes, ma'am.

16 MS. O'SHEA: It's fine, Your Honor. I'll hear what
17 the documents are. But until we can ascertain what they
18 are, I might have some sort of basis for objecting.

19 THE COURT: Well, you're going to have to -- are you
20 going to put these documents physically into evidence?

21 MS. PEIFFER: Your Honor, they are already in
22 evidence. But I would be happy to put in additional
23 copies.

24 THE COURT: Well, they couldn't possibly be in
25 evidence because you've introduced no evidence in this

DIRECT EXAMINATION OF DR. RUBLE

24

1 hearing yet. They could be appended to your documents.

2 MS. PEIFFER: They are.

3 THE COURT: To your filings.

4 MS. PEIFFER: And we can introduce them as evidence.

5 THE COURT: Well, I think you should introduce them
6 as evidence. And specifically identify which document
7 you're referring to before the doctor gives any kind of an
8 explanation, all right?

9 MS. PEIFFER: Absolutely.

10 THE COURT: Go right ahead.

11 BY MS. PEIFFER:

12 Q So, Dr. Ruble, did you have occasion to review a
13 photograph of three bottles?

14 A A photograph of three vials was supplied to me. Yes,
15 ma'am.

16 Q And what did you see in that photograph?

17 A According to the label --

18 THE COURT: Hold on just one second.

19 Do you have that document?

20 MS. PEIFFER: Your Honor, we're getting it.

21 THE COURT: All right. Let's have Ms. Pizzini mark
22 it as an exhibit, and make it a part of the record in the
23 case.

24 MS. PEIFFER: Okay. Thank you. I'm sorry. I'm not
25 use to doing this over the telephone.

DIRECT EXAMINATION OF DR. RUBLE

25

1 THE COURT: I understand that. But at some point,
2 another Court may need to review my decision one way or
3 the other. We want to make a complete record, and a clear
4 record, okay?

5 MS. PEIFFER: Absolutely.

6 THE COURT: All right.

7 DR. RUBLE: Ms. Peiffer?

8 MS. PEIFFER: Yes. Just one moment.

9 DR. RUBLE: Okay. Yes, ma'am.

10 THE COURT: So this document will be marked as your
11 Exhibit 1.

12 Is there any objection, Ms. O'Shea?

13 MS. O'SHEA: No, sir.

14 THE COURT: It will be received as your exhibit
15 without objection.

16 (Plaintiff's Exhibit 1 is received.)

17 THE COURT: Go ahead and ask the Doctor the next
18 question.

19 MS. PEIFFER: I think, if it's acceptable to Your
20 Honor, since this is a little bit awkward, we'll just go
21 ahead and put -- there are only three documents. We can
22 put them into evidence, and then we can --

23 THE COURT: Yes, ma'am. Go right ahead. Put them
24 all in at one time.

25 MS. PEIFFER: Great. I think that will be most

efficient.

BY MS. PEIFFER:

Q Dr. Ruble, did you also have occasion to review a form that was a Drug Enforcement Administration order form?

A Yes, Ms. Peiffer. That form appears to be a copy of a DEA 222 form.

THE COURT: And that's the form that you saw, Doctor, is that correct?

DR. RUBLE: I believe so, Your Honor.

THE COURT: All right.

Any objection, Ms. O'Shea?

MS. O'SHEA: There's not, Your Honor.

THE COURT: That will be received.

(Plaintiff's Exhibit 2 is received.)

THE COURT: All right. Give it to the Marshal. It will be made a part of the record.

Next document.

BY MS. PEIFFER:

Q And the last document that I'm going to ask you about right now is a laboratory report with a number of redactions, but it concerns pentobarbital Lot Number 04142015, ampersand, 8.

THE COURT: What was the last thing you said?

MS. PEIFFER: Ampersand 8.

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1 THE COURT: Ampersand?

2 MS. PEIFFER: The "at" symbol. Yes.

3 THE COURT: Okay.

4 Did you see that document, Doctor?

5 DR. RUBLE: Yes, Your Honor, I did.

6 THE COURT: All right.

7 Any objection, Ms. O'Shea?

8 MS. O'SHEA: No, Your Honor.

9 THE COURT: Be received.

10 (Plaintiff's Exhibit 3 is received.)

11 THE COURT: Go right ahead.

12 DR. RUBLE: Yes, Ms. Peiffer. I'm waiting.

13 MS. PEIFFER: Just one moment.

14 DR. RUBLE: You bet.

15 THE COURT: All right, Ms. Peiffer, go ahead with
16 your next question of Dr. Ruble.

17 BY MS. PEIFFER:

18 Q Dr. Ruble, going back to the photograph that you
19 reviewed. What information were you able to glean from
20 looking at the bottles in the photograph?

21 A I have a black -- I believe that the document
22 transmitted to me was in color. The one I'm currently
23 looking at is in black and white. But those appear to be
24 amber colored glass vials commonly used for the
25 formulation of injections for intravenous, or what we

1 call, parenteral administration, typically injected into
2 the bloodstream.

3 They are labeled with what appeared to be exactly the
4 same identical labels that identify the solution in there
5 as being pentobarbital as the -- what we call the active
6 pharmaceutical ingredients in there. A concentration of
7 them, which is labeled as 50 milligrams per millimeter of
8 volume.

9 The next line down has three initials, or an acronym,
10 which is MDV, set in solution 50 mls, which would indicate
11 that it would be filled with a 50 ml volume. The MDV, at
12 least in this field or art, is normally associated with a
13 product being identified as a multi-dose vial.

14 The third line down below has a lot number, which is
15 the same lot number that Ms. Peiffer just read off in
16 relation to a laboratory report, that being 04142015, with
17 an @ sign, and the number 8. And then what is called a
18 use by date, which is 4/14/2016.

19 Q Thank you.

20 A Yes, ma'am. And --

21 Q I'm sorry. Was there something else that you
22 observed about those bottles?

23 A Well, the bottom edge of the label appears to have
24 been cut or scoriated in some fashion with a razor blade.
25 Presumably that was to redact identifying information of

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1 some other element. So what I would say is that normally
2 in compounding perspectives, there would be additional
3 information that would need to be required on the label,
4 which presumably was redacted in some fashion for the
5 purposes of this proceeding.

6 Q And from the lot number and the use by date, what can
7 you tell us about the time between the creation of the
8 mixture and the use by date?

9 A Well, these labels are familiar to me in my practice.
10 I can't say with 100% certainty, but they are very similar
11 in format and structure to labels generated by a computer
12 software program that is commonly utilized by compounding
13 pharmacists. The formatting of them, obviously that could
14 be duplicated through other programs, but it's very common
15 of compounding pharmacies to use this particular program
16 on here.

17 The lot number itself, again, not knowing with
18 certainty on this, but a high belief of certainty that
19 that lot number, as is customarily done in this practice,
20 the lot number would indicate the date upon which the
21 compounded sterile preparation was actually prepared. So
22 I would interpret that as saying that the preparation was
23 made on the 14th day of April of 2015 at 8:00 a.m., or
24 perhaps not exactly the minute of 8:00 a.m., but in
25 essence at 8:00 a.m. in the morning.

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1 The use by date is then extended approximately to one
2 year from the date of -- if we go in that customary
3 process.

4 Q What is the difference between compounded
5 pentobarbital and manufactured pentobarbital?

6 A That is -- that is a very good question. A
7 compounded -- well, many times incorrectly -- although you
8 didn't use it incorrectly, it is incorrectly stated that
9 these are compounded products. And really, these are
10 compounded preparations. That's what's distinguished in
11 The United States Pharmacopeia, which has a lot of
12 guidance about compounding practices.

13 So these are things -- these are preparations that
14 are made that are intended for use in some sort of a
15 patient. Normally a human patient, but it can also
16 incorporate in an animal patient. Preparations that
17 include an active pharmaceutical ingredient that are made
18 in some fashion to render it so that it can be
19 administered to a patient.

20 The same is true of a commercial product, but it is
21 made under the blueprint and under the processes that
22 involve good manufacturing practices. That's why they're
23 called an article of manufacture or a commercial product,
24 whereas these are called compounded preparations.

25 Commonality to them, they involve an active

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1 pharmaceutical ingredient. So we're all aware that there
2 are commercial products for pentobarbital, and that they
3 are made in the strength of 50 milligrams per ml. They
4 can come in a volume size of 50 milliliters.

5 This is, in essence, what is intended to be, or at
6 least, a substitute product for a substitute preparation
7 for the product that has tried to emulate it as close as
8 can be done, but they are not considered the same, if you
9 will, drug in this case. We will look at it in that way.
10 It is a preparation as opposed to a product. You have an
11 API. The same concentration as stated on the label.

12 Compounding preparations typically go in accordance
13 with the set of USP guidelines, a specific chapter in
14 there that is called 797, that deals with the preparation
15 of sterile formulations. It was released by The United
16 States Pharmacopeia as a general guidance chapter in 2004.
17 It did not become mandatory for pharmacies -- for
18 pharmacists to comply with until roughly 2008. And
19 various states have different levels of incorporation of
20 this into their pharmacy practice acts.

21 Good manufacturing practices, which is what
22 commercial products are made by, were first introduced in
23 1962 in --

24 THE COURT: Doctor, could you hold off a second?

25 DR. RUBLE: Yes, Your Honor.

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1 THE COURT: I think this a little bit beyond the
2 initial question that you asked. I think we should
3 proceed by question and answer. So why don't you ask your
4 next question.

5 MS. PEIFFER: Of course.

6 BY MS. PEIFFER:

7 Q Is there a difference between compounded
8 pentobarbital and manufactured pentobarbital in terms of
9 F.D.A. regulations?

10 A A commercial product undergoes a formal evaluation
11 prior to being allowed in interstate commerce. It is a
12 licensing process. So it is a formal approval process
13 that the F.D.A. conducts to allow that product to move
14 through interstate commerce.

15 Compounded preparations are specifically exempted
16 under the Food, Drug, and Cosmetic Act from the same
17 licensing process. So, in essence, they are given an
18 exemption, or a waiver from licensing, by the F.D.A. They
19 are not formally evaluated by the F.D.A.

20 Q And in terms of that F.D.A. evaluation process, what
21 does that mean in terms of the reliability and variability
22 of compounded batches of pentobarbital versus a
23 manufactured pharmaceutical that is labeled pentobarbital?

24 A Yeah, I'm not -- I'm not sure of a specific answer.
25 Can you rephrase that? Let me see if I can give you a

1 more specific and narrow answer to the question.

2 Q Of course. Is there a difference in terms of how
3 these materials are handled and treated, and how reliable
4 they are if on the one hand you have a manufactured
5 pharmaceutical pentobarbital, and on the other you have a
6 compounded mixture of pentobarbital?

7 A Okay. Thank you for rephrasing the question on
8 there. My -- I'll try to keep this answer quick.

9 In this respect, according to the preparation and the
10 evaluation from a commercial product, many times they're
11 produced in accordance with what's called good
12 manufacturing practices, which are very detailed pages.
13 And more often than not, they are proceeded by the
14 development of a monograph in The United States
15 Pharmacopeia, which have very exacting requirements for
16 the commercial products in terms of what their potency may
17 be, and how they are analyzed qualitatively and
18 quantitatively to insure that they meet the guidelines
19 that are delineated through a scientific document, the
20 monograph. And I believe that that may come up later on.

21 Compounded preparations, on the other hand, are --
22 compounded preparations proceed by what's called a general
23 guidance in their process. So we -- there isn't
24 necessarily a published document from the USP that tells
25 pharmacists here's how you exactly compound pentobarbital.

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1 There are, on occasion, published recipes that are out
2 there. And in fact, I've searched wide and far for a
3 published recipe on compounding of pentobarbital, and it's
4 not out there. At least not that I've encountered.

5 Having said all that, the tolerance limit in terms of
6 what the error limits are, they go by a general nature of
7 plus or minus 10%; whereas, the tolerance limits can be
8 much more narrow from the standpoint with commercial
9 products.

10 Q And could you briefly describe the process of
11 compounding pentobarbital, and how APIs are used and what
12 APIs are?

13 A An API, by definition under USP and other texts,
14 stands for Active Pharmaceutical Ingredients. So one way
15 to think about these -- and I'm heeding Your Honor's
16 instructions, and I will keep this as narrow as possible.
17 Please cut me off if this exceeds the scope.

18 An API, an Active Pharmaceutical Ingredient, is
19 really the chemical that's involved in the formulation.
20 But the formulation itself we have to think of as a
21 system. It involves many components. In this case, a
22 diluent or a solution.

23 There may be other inactive ingredients in there that
24 don't -- that aren't intended to affect the body of the
25 patient or their physiology in some way, but help, for

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1 example, to keep the drug in solution. There could be
2 preservatives added sometimes. That's not always true.
3 So there are many elements that could go into it, into the
4 formulation, the creation of the final preparation. Those
5 are delineated in the commercial, what we call, package
6 insert, for commercially made pentobarbital. I have no
7 way of knowing what those other ingredients are, based on
8 the label. All I know is in this case that the
9 pentobarbital, active pharmaceutical ingredient, is
10 labeled as being in the solution.

11 I alluded to when I looked at the labels and said
12 that this is classified as a multi-dose vial, that would
13 imply, although I don't know with certainty, that there is
14 some sort of a preservative that's in this. That would
15 tend to perhaps distinguish it somewhat from the
16 commercial products, depending on the formulation. Many
17 of the commercial products do not necessarily have
18 preservatives in them. They have citric acid, and other
19 kinds of elements in there, that help to buffer the pH.
20 But that already could be a potential distinguishing
21 element, saying that they're not exactly the same
22 formulations.

23 So anyway, yes.

24 Q And could you just describe how the environment in
25 which, or the place, the compounding pharmacy, where a

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1 substance or mixture is made, could affect how the mixture
2 works?

3 A Sure. Thank you, Ms. Peiffer.

4 In accordance with the USP 797 document, I stated
5 that before, which gives general guidance on the
6 compounding of sterile preparation, preparations that are
7 made that are sterilely compounded that begin with a bulk
8 powder form of an active ingredient, which is likely what
9 occurred in this scenario. And again, I don't have the
10 recipe that the pharmacy actually used in preparing this.
11 I would presume that's the case. That it began what a
12 sterile -- pardon me. That it began with a bulk powder
13 that is a pharmaceutical grade chemical, but is not
14 necessarily sterile.

15 That amount would be weighed out. It would be mixed
16 with the proper diluent, and whatever other elements are
17 called for in the recipe, and it would be formulated
18 together.

19 That type of compounding has to occur in a very
20 controlled, engineering controlled, facility in terms of
21 the atmospheres that are created. It has to be a sterile
22 atmosphere. There are primary and secondary engineering
23 controls. It is a very technical process. In essence,
24 these are the embodiments of clean rooms.

25 In most circumstances, they're as clean and as

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1 sterile as an operating room. That is the equivalent to
2 them. It takes people of -- it takes professionals of
3 good skill and good knowledge, to understanding behind
4 those engineering dynamics and incorporation of it, in
5 order to successfully practice to create this system.

6 When a compounded sterile preparation begins, it's
7 formulated beginning with an API that is of non-sterile
8 character to begin with. It is deemed to be what's called
9 a high-risk compounded preparation. High-risk meaning
10 that the risk is associated that there is a potential
11 likelihood for contamination of a process, and extra due
12 diligence and care needs to be taken to minimize that.

13 That includes the process of what we call terminal
14 sterilization. There are a number of ways within which
15 that can be conducted. But once the powder has been
16 dissolved in the solution, the solution has been created,
17 it needs to be in some fashion sterilized before it can be
18 administered to the patient.

19 Sterilization can happen a number of different ways.
20 I can't say all compounding pharmacies, but in most of
21 them it is conducted through terminal sterilization,
22 meaning that it's passed through a filter and then
23 placed -- and it would be placed into the vial as depicted
24 in the photograph that we have in evidence.

25 There can be other forms -- other ways to sterilize,

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1 including autoclaves. And there are a few other
2 methodologies which are less commonly used. But the
3 vast -- the vast bulk of it is through a filter that is
4 sterilizing. That would remove the bacteria from the
5 vials.

6 Q And would compounded pentobarbital be a high-risk
7 sterile injectable?

8 A I would classify it as such if it had been derived
9 from a powder form initially, which I can't think of any
10 other way that it would be compounded. Manufacturers, to
11 my knowledge, at least from a bulk standpoint, don't
12 provide it in a liquid solubilized form. I believe they
13 don't. Where we've known about it being available in the
14 past through various kinds of pharmacy vendors, to my
15 knowledge, it was supplied as a solid powder form for
16 compounding purposes.

17 Q And you mentioned "*active pharmaceutical ingredients*"
18 in bulk powders. Are there any risks associated with
19 using these ingredients? Are you able to tell very much
20 about the ingredients themselves?

21 A I'm sorry. I didn't follow the question completely.

22 I would say that in general there are two really
23 overarching concerns that we worry about. There are many,
24 but two really primary concerns. One would be is what's
25 called the sterility of the finished product, and the

1 stability of the finished product.

2 The sterility would go to could it have been
3 contaminated at some point during the preparation process,
4 or after its preparation, as a result of the conditions of
5 its storage or, if you will, chain of custody. I don't
6 mean it from a legal sense. I mean it from the
7 perspective of how is it actually stored, was it done
8 under the properly designated conditions through the USP,
9 and through other guidance documents. So the sterility of
10 the product, and whether or not there's a risk that
11 microorganisms could have been somehow introduced into the
12 process.

13 We would like to say that it's 100% effective with a
14 sterilization filtered process, but that's not always
15 true. They are very effective, but they're not always
16 complete. That's why we have to have ongoing surveillance
17 to make sure the products remain fit for their intended
18 use. So sterility is one element of the process.

19 Sterility can be from what are called -- can be
20 contaminated from the standpoint of microorganisms. They
21 can also be contaminated from the perspective of things
22 that are not necessarily growth-capable microorganisms,
23 but maybe dust particles or other particulates. Things
24 that aren't necessarily living, but they can cause illness
25 or disease in the patient through a lot of different

1 mechanisms on there. That's on the one side.

2 The other concern would be, at least in the
3 compounding process, is that it was prepared in such a way
4 to minimize the decay in its potency. Now, over time, all
5 drugs will decay to some degree. And depending upon what
6 their dosage form is, some decay much more quickly than
7 others do. For most medications that we use, and
8 pentobarbital is included in this, they are some sort of
9 either organic acids or an organic base.

10 Those particular types of chemical compounds are
11 highly prone to degradation when they are exposed to
12 water. So water is convenient. It makes this an easy to
13 administer -- easier to administer dosage form because it
14 puts it in a soluble form that can be drawn up into a
15 syringe that can be injected into a patient. But at the
16 same time, that water medium is the medium that promotes
17 degradation. It's through what's called a hydrolytic
18 reaction.

19 THE COURT: I think, Ms. Peiffer, we need to proceed
20 by question and answer at this point.

21 DR. RUBLE: Thank you, Your Honor. Sorry.

22 THE COURT: Why don't you focus your questions rather
23 than just let the professor lecture.

24 MS. PEIFFER: Of course.

25 BY MS. PEIFFER:

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1 Q Is there a difference between sterility testing and
2 potency testing?

3 A A sterility test would be used to test to see if
4 there are contaminants in the final preparation.

5 A potency test would be used in some way to
6 quantitatively or numerically quantify how much of the
7 original API is still there in the solution.

8 Q And are those different tests that are performed on a
9 mixture?

10 A I have not physically performed those tests. I
11 believe I'm well-read on those tests and understand it,
12 and educate professionals about those kinds of tests, but
13 they are two separate kinds of testing procedures that are
14 performed.

15 Q I want to turn to a term you mentioned earlier,
16 "*beyond use date*". Can you please describe what that
17 means.

18 A Beyond use dates are applied to compounded
19 preparations. And they are the date beyond which we don't
20 have as much faith, I guess, if you will, or confidence,
21 that the product still remains fit for the intended use of
22 it. And that could either be used to concerns about
23 sterility, but more often than not, they're due to
24 concerns about whether or not the product retains the
25 potency, as specified, that needs to be maintained.

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1 That is differentiated from an expiration date. An
2 expiration date is a different entity.

3 Q What is the difference?

4 A An expiration date is applied to a commercial
5 product. And it is the result of very rigorous testing
6 that occurs by a chemical -- by a pharmaceutical
7 manufacturer under really sophisticated laboratory
8 instrumentation that they have available to them, HPLC.
9 And there are a number of other tests involved.

10 Q And could you describe briefly how a beyond use date
11 is determined for a high-risk sterile injectable?

12 A Well, there are -- for a high-risk sterile compounded
13 preparation, a beyond use date in the absence of specific
14 scientific testing, are established through what's called
15 an empiric guideline. So it's just basically, in
16 Chapter 797, as I previously discussed, there are general
17 guidances about how we apply beyond use dating.

18 So we don't have specific testing on the preparation.
19 The beyond use dating for a high-risk compound sterile
20 preparation, if the preparation is maintained at room
21 temperature, it is deemed a beyond use date of 24 hours or
22 less. If it is refrigerated, it is actually called a
23 controlled cool temper. But we all interpret that as
24 refrigerated. That means that it is available for three
25 days from the date of preparation. And if it were somehow

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1 to be frozen in a solid frozen state, it could be extended
2 45 days.

3 Now, where there is specific quantitative studies
4 done on it through a sterility test and a potency test, on
5 occasion those dates can be extended.

6 Q And what kind of testing would need to be done in
7 order to extend a beyond use date beyond the period you
8 just described?

9 A Well, they would be both a -- well, they, whoever.
10 Typically, it would be the pharmacy compounder that's
11 preparing it. If they were going to extend that, they
12 would have to do sterility testing and potency testing.

13 Q And can --

14 A The beyond potency would be called a stability test.
15 So there would be at least a couple potency
16 determinations. There are other methodologies for it, but
17 that's one -- one way.

18 Q Can compounded pentobarbital be frozen?

19 A I haven't specifically evaluated that, frozen and how
20 it retains its stability. Very few drugs can be frozen
21 for long periods of time. This would be -- just based on
22 my experience, I would not want to do it because I think
23 it could potentially impact the overall stability of this
24 drug.

25 Freezing a chemical compound, subjecting it to those

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1 kinds of forces, which put enormous strain and tension on
2 the chemical makeup of it, so before I froze it, I would
3 want to see some very specific scientific data saying that
4 that was possible. And I'm not aware of any -- of that
5 data being published.

6 Q So because of the restriction on freezing, if there
7 were not extended sterility and potency testing, what
8 would the beyond use date for compounded pentobarbital be?

9 A For compounded high-risk pentobarbital, it would be
10 three days, or 72 hours, at a controlled cold temperature.

11 Q Thank you.

12 A You're welcome.

13 Q So you mentioned earlier that when you reviewed these
14 records, you saw a beyond use date of April 14, 2016.

15 What is your opinion about this beyond use date?

16 THE COURT: With respect to what?

17 MS. PEIFFER: With respect to whether it is
18 reasonable, or would require further investigation.

19 THE COURT: What specific sample are you talking
20 about? Samples in general?

21 MS. PEIFFER: In Exhibit 1.

22 THE COURT: Okay. Go ahead.

23 MS. O'SHEA: I'm sorry.

24 THE COURT: Yes, ma'am.

25 MS. O'SHEA: Your Honor, I would object because he

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1 has just testified that the beyond use date is going to
2 depend upon how it is compounded, how it is manufactured.
3 He can't give an opinion as to the validity of the beyond
4 use date because he doesn't have that information. It
5 would be speculation.

6 THE COURT: I think with respect to this sample, that
7 goes to the weight and not the admissibility. Objection
8 is overruled.

9 Doctor, you may answer.

10 DR. RUBLE: Thank you, Your Honor.

11 Ms. Peiffer, could you just repeat the question for
12 me so I make sure I get it right?

13 MS. PEIFFER: Of course.

14 BY MS. PEIFFER:

15 Q When you saw the beyond use date of 4/14/2016, which
16 was a year after manufacture, what was your opinion about
17 whether that is reasonable?

18 A It seemed at the extreme end of any possibility that
19 I might do. I'm customary to seeing compounded
20 preparations more in sort of the three to six month range.
21 I'm not suggesting that a 1-year expiration date is
22 impossible, but I would certainly, at least from my own
23 due diligence process, before I utilize that in a direct
24 patient care would want a little -- to know more about how
25 it was formulated.

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1 I mentioned earlier that it said that it was a
2 multi-dose vial. That's certainly an element --

3 THE COURT: My objection is sustained. He's now
4 beyond your question. Next question.

5 DR. RUBLE: Sorry, Your Honor.

6 BY MS. PEIFFER:

7 Q And what would happen to a drug after its beyond use
8 date passes?

9 A What would happen to it?

10 Q Yes.

11 A Well, it's hard to know for certain without specific
12 testing. It could be related to either -- typically, it's
13 related to -- it does not have the potency that we would
14 want it to have to achieve its effect.

15 Q And you had occasion to review a lab report last
16 night that is now Exhibit 3, is that correct?

17 A I believe so. Yes. Exhibit 3. That would be the
18 previously mentioned, or identified, laboratory report?

19 Q Yes. Exhibit 3. From your review of that lab
20 report, can --

21 THE COURT: He doesn't have the document in front of
22 him, so we need to make sure we're looking at the same
23 document.

24 Doctor, that's the document that's dated April 27,
25 2015. Sir, do you have that?

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1 DR. RUBLE: I do, Your Honor. I do have it in front
2 of me, a printed copy, Your Honor.

3 THE COURT: Okay.

4 Go right ahead then.

5 BY MS. PEIFFER:

6 Q According to that document, were any sterility tests
7 performed on the substance tested?

8 A I do not see any indicated on this laboratory report.

9 Q Was there a potency test performed?

10 A There is a potency test that is indicated on here of
11 94.6%.

12 Q And where does that fall within the acceptable range
13 for compounded pentobarbital?

14 A I supposed it would depend on what guidelines are
15 being utilized here. If it's in The United States
16 Pharmacopeia monograph, those are stated as being between
17 92% to 108%.

18 If there are 797 guidelines that are being involved
19 or incorporated, those would be -- those would be stated
20 at a plus or minus of 10% of the label percent -- plus or
21 minus 10% of the label amount, meaning that a range of 90%
22 to 110%.

23 Q And as a compounded substance ages, what happens to
24 the potency?

25 A We expect the potency to decrease. I think that's

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borne itself out in nearly every scientific matter. We don't see potency increase, to my knowledge, or at least that's not in any regards to customary routine.

Q Does the potency of the drug relate to the conditions in which it is kept?

A Absolutely. Environmental factors are big influences on the potency. So those would be light, heat, temperature, the chemical conditions in terms of pH. There are a number of other elements.

Q And in your knowledge about compounding and testing, have you heard reports that testing laboratories have had certain issues?

THE COURT: Objection sustained unless this is simply offered not for the truth of the matter, but only as a foundation for an opinion he's going to give. I'm not going to accept it for the truth of the matter. But if he relied upon that in an opinion he's going to give, I will overrule the objection.

Which is it?

MS. PEIFFER: Your Honor, I will withdraw the question -

THE COURT: That's fine. Go ahead.

MS. PEIFFER: - and rephrase.

THE COURT: Go ahead.

BY MS. PEIFFER:

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1 Q Are you familiar with the testing done by independent
2 laboratories of compounded substances, and the F.D.A.
3 regulation of these laboratories?

4 A Not with intimate details. I am generally aware of
5 them in terms of advising pharmacy licensees relative to
6 compounding manners about the need to test things. And
7 quite normally, that is done through an outsourced
8 Contracted Laboratory that has some element of oversight
9 by the F.D.A., as well as other administrative agencies.

10 Q If the F.D.A. issues a Form 483 report about a
11 testing facility, what does that mean?

12 A Well, Form 483 reports are not just for testing
13 facilities. They're also -- they are an expression of
14 concern issued by the F.D.A. to some sort of regulated
15 site, whether it be manufacturing, pharmaceutical
16 manufacturer, or a laboratory. It could mean -- they have
17 even been issued to compounding pharmacies in the past.
18 And those are expressions of concern which required
19 detailed responses, including corrective actions, by the
20 person or entity that it's been issued to.

21 MS. PEIFFER: Thank you.

22 Court's indulgence for a moment?

23 THE COURT: Yes, ma'am. Go right ahead.

24 BY MS. PEIFFER:

25 Q Just to clarify a matter of acoustics. I was asking

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1 you about 483 reports. Is that the question to which you
2 were responding?

3 A Those are the -- that's the number that I'm familiar
4 with is 483.

5 Q Okay.

6 A That's correct.

7 Q Thank you. I think I might have misheard.

8 THE COURT: All right.

9 MS. PEIFFER: No further questions.

10 THE COURT: All right.

11 Ms. O'Shea, cross-examination of the Doctor.

12 **CROSS-EXAMINATION**

13 BY MS. O'SHEA:

14 Q Good afternoon, Dr. Ruble. My name is Margaret
15 O'Shea. I'm with the Attorney General's Office. I'm
16 going to ask you a few questions about what you just
17 testified about.

18 A Yes, ma'am.

19 Q When we were discussing, or you were discussing, the
20 potency of compounded products, you indicated that potency
21 relates to how much of the substance went into the
22 solution, is that correct?

23 A I believe that's correct. How much -- when the
24 product is chemically analyzed, the mass -- the amount of
25 that substance in the overall concentration of the -- in

1 the amount analyzed.

2 Q Okay. So over time, you said the potency of the
3 subject can decrease. Would it precipitate out of
4 solution if that were happening?

5 A That's one way within which the -- it could so then
6 come out of a solution form and precipitate into a solid
7 form. It's not -- yeah. That would be one way.

8 It could be chemically altered so that perhaps it is
9 altered to another chemical compound, which may or may not
10 have activity in the human body.

11 Q So if another chemical compound were introduced into
12 what was already inside that particular compounded vial,
13 is that what you just said?

14 A Well, that would be one way of it. The actual
15 hydrolytic reaction could also convert it to another
16 chemical compound, which is then not active anymore.

17 Q All right. You had indicated that circumstances and
18 environmental conditions are very important to maintaining
19 the potency of the compounded pharmaceutical, correct?

20 A That's correct, ma'am.

21 Q So one of those is sunlight, for example. So if you
22 take a compounded product and expose it to sunlight, that
23 could decrease its potency, yes?

24 A That would be one way. If I said sunlight, please
25 let me correct that. I hope I didn't imply that it was

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1 light. So sunlight would be one way. Even other kinds of
2 light forms, through florescent lights, and others, have
3 some element of causing degradation as well.

4 Q Certainly. Or if it were exposed to extreme cold or
5 heat, correct?

6 A Those would be other manifestations we would be
7 concerned with. Yes, ma'am.

8 Q So would it be fair to say that if a substance were
9 kept out of the sunlight, out the light, and if it were
10 maintained at approximately room temperature, then that
11 would lessen your concerns regarding the decrease in
12 potency of that subject?

13 A I don't know about the room temperature standpoint.
14 Some drugs, if they have been specifically analyzed, can
15 remain -- can have some -- well, all drugs will have a
16 decrees in their potency over time. At room temperature,
17 some will hold that potency for a while. But I would say
18 the answer to your question is it is preferable under most
19 circumstances to have these medications refrigerated.

20 Q What about pentobarbital? Do you have any knowledge
21 of that?

22 A Well, pentobarbital, if we're compounding it in
23 accordance with the API guidelines of USP 797, we would
24 want to keep it refrigerated. There are some scientific
25 reports that have shown, or at least ones that I know of,

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1 that have talked about it being stable for up to 31 days
2 at room temperature, at least in a glass vial under those
3 circumstances.

4 I am not -- there may be longer duration reports.
5 I'm not specifically aware of them. Thirty-one days is
6 the longest report that I have seen that has been
7 published.

8 Q Have you ever made compounded pentobarbital?

9 A I have not made it beginning from sterile bulk
10 powder. I have compounded it from the commercial sources
11 to change the concentrations of it for use in clinical
12 administration of patients in neuro intensive care units.
13 But I've not made it from sterile bulk powder. I have,
14 however, compounded and made other high-risk sterile
15 formulations beginning with bulk powder.

16 Q I understand. We're here today about pentobarbital.
17 So to the extent we can, I'd like to focus your answers on
18 that substance.

19 A I have not made it before. That's correct.

20 Q Are you familiar with compounding pharmacies in the
21 State of Texas? Have you ever visited one?

22 A I have not visited one in the State of Texas, ma'am.
23 I'm familiar with names.

24 Q As a pharmacist or a pharmacologist, you view
25 pentobarbital as basically a drug, a medication, correct?

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1 A From clinical applications, yes. I know that my own
2 professional guidelines ask that we not refer to it as a
3 drug or medication. They would prefer that we refer to it
4 as a chemical.

5 Q As a chemical. But it is intended for use in humans,
6 correct, or animals, as you said in the beginning?

7 A Well, yes, from a -- for a clinical application to a
8 patient. Yes, ma'am.

9 Q And when you use "*a clinical application*," you mean
10 for purposes of practicing medicine, correct?

11 A That's correct. To treat some sort of illness or
12 condition. Yes. Yes, ma'am.

13 Q And so your concerns about sterility and potency
14 aren't tied to the fact that the substances are, in your
15 view, going to be used in the practice of medicine,
16 correct?

17 A Yes, ma'am. That's correct.

18 Q If compounded pentobarbital is made correctly, it is
19 as efficacious as manufactured pentobarbital, is that
20 correct?

21 A I am not aware of a head-to-head study that compares,
22 you know, the clinical efficacy of a compounded
23 formulation to the commercial product.

24 Q You don't know?

25 A I don't know.

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1 MS. O'SHEA: Okay. I don't have any other questions.

2 THE COURT: All right.

3 Ms. Peiffer, any redirect of the Doctor?

4 MS. PEIFFER: Yes. Several questions.

5 THE COURT: All right. Go right ahead then.

6 **REDIRECT EXAMINATION**

7 BY MS. PEIFFER:

8 Q Just to clarify, Dr. Ruble, if a drug has -- I'm
9 sorry, a compounded mixture has decreased in potency,
10 would it work as the product was intended to work?

11 A It would depend on what that potency is. There are
12 these guidelines and cut offs. I mentioned 92%, according
13 to the USP monograph, or to 90% if it is according to 797.

14 There is a retention of some amount of active
15 pharmaceutical ingredients, but those cut offs or
16 guidelines is, I guess, concluded that it's not fit for
17 meeting its intended use.

18 Q What do you mean not fit for intended use?

19 A It doesn't have the potency to achieve the expected
20 or anticipated results of the application of it.

21 Q Would that be true no matter how someone used the
22 drug? Whether it was used as a medication, or for some
23 other reason?

24 A Well, if we're using it in a clinical application to
25 treat a patient's illness, we would not use it if it were

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1 expired or if it were beyond the beyond use date. We
2 would not do that with a patient.

3 Q Is there also a risk if it were not used for a
4 medical purpose to treat a patient, would a drug whose
5 potency decreased still potentially not work the way it's
6 intended?

7 MS. O'SHEA: Well, Your Honor, I would object. He
8 just testified that the intended use is for clinical
9 purposes.

10 THE COURT: I think you have to rephrase your
11 question and focus it just a bit.

12 MS. PEIFFER: Thank you.

13 BY MS. PEIFFER:

14 Q If a drug is intended, for example, to render someone
15 unconscious, and it has degraded in potency beyond the
16 acceptable guidelines, is it a risk that that drug being
17 used that has degraded would not render a person
18 unconscious?

19 A Well, we would expect that. I don't know that I am
20 fully qualified to answer that question from that
21 standpoint in terms of the prescribing intent of the
22 prescriber. I would just say that I would have some
23 concerns as a pharmacist whether or not that particular
24 product would have the API necessary to meet what the
25 physician's or the prescriber's order for therapy would

1 be.

2 Q And based on your research and your experience in the
3 field, do you consider yourself able to discuss the
4 requirements, such as potency and sterility of compounded
5 substances, even substances you have not made yourself?

6 THE COURT: For what purpose?

7 MS. PEIFFER: To opine on the effectiveness, potency,
8 and sterility, and how the compounded substances work.

9 THE COURT: For what purpose?

10 MS. PEIFFER: I'm sorry, Your Honor. I don't think I
11 understand what you're asking.

12 THE COURT: You're talking about the potency of the
13 drug and its effectiveness, okay?

14 MS. PEIFFER: Right.

15 THE COURT: For what purpose?

16 MS. PEIFFER: For any purpose.

17 THE COURT: Okay. For any purpose.

18 Do you understand the question, Dr. Ruble?

19 DR. RUBLE: If I may ask, Ms. Peiffer, with the
20 Court's indulgence, to repeat the question just so I have
21 it clear what is being asked of me.

22 MS. PEIFFER: Of course. I don't know if I can say
23 it exactly.

24 BY MS. PEIFFER:

25 Q But based on your professional experience, your

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1 research, and the things that you have relied on for your
2 experience in the past 20 years, do you consider yourself
3 qualified to opine on issues like potency and sterility
4 and stability in compounded substances, even for
5 substances you have not made yourself and mixed yourself?

6 A Well, I would hope so from the standpoint that I'm
7 educating the next generation of pharmacy professionals
8 who will be undertaking those activities in many
9 circumstances to provide those preparations in direct
10 patient care activities. They've got to learn it from
11 somewhere. One would hope that their instructor has the
12 requisite expertise, and I have to say that I do have that
13 to project to them.

14 Q And one last question, Dr. Ruble. You have been
15 given three documents to review, and this Court has
16 labeled them Exhibits 1, 2, and 3. If you were given
17 those documents in your practice, and that was the only
18 information that you had about a particular mixture that
19 you were planning to use, would you think further
20 investigation is reasonable and necessary before using
21 that substance?

22 MS. O'SHEA: Your Honor, I --

23 THE COURT: Excuse me.

24 For what purpose?

25 MS. PEIFFER: Again, for any purpose, Your Honor.

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1 THE COURT: Any purpose?

2 Very broad question, Doctor.

3 MS. PEIFFER: For the purpose that the drug is
4 intended.

5 MS. O'SHEA: I object as to relevance.

6 THE COURT: Well, as presented, it's a bit on the
7 vague side. I don't know whether it's relevant or not
8 until she is able to relate it.

9 Are we talking about a patient in surgery? Or are we
10 talking about, frankly, an execution, as we have here? I
11 mean, they are totally different purposes. You're going
12 to have to narrow your question, and focus it a bit more
13 on the facts before the Court.

14 MS. PEIFFER: Of course.

15 THE COURT: Rephrase your question, and the Doctor
16 will answer.

17 BY MS. PEIFFER:

18 Q Given the documents that you have reviewed, you saw
19 that you -- you opined earlier that there was no sterility
20 testing. Would you have concerns about using that
21 substance if you were trying to render someone
22 unconscious?

23 THE COURT: Objection is overruled.

24 Go ahead, Doctor. You may answer.

25 DR. RUBLE: Thank you, Your Honor.

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1 A The due diligence process on this is a clinical
2 judgment can manifest in different ways. I would say that
3 as I educate my students in conducting their own due
4 diligence in determining these things, there are a number
5 of factors I would want to know. I don't know the name of
6 the pharmacy in this case. And obviously, I'm not asking
7 for that. But the reputation of the provider who is
8 providing the preparation can go along with part of that
9 consideration.

10 Not knowing the recipe here, for me, many times in
11 understanding the compounded formulations, I would want to
12 know how it is prepared, what other ingredients may or may
13 not be in it. We have that capability with commercial
14 products because they are identified in a package insert.
15 We don't necessarily have that with compounded
16 preparations. So those would be a couple of the elements.

17 You mentioned sterility testing on there, too. We
18 don't necessarily always have access to that information
19 as compounders, but we would like -- that would be part of
20 the basis of the reputation of the provider if they've had
21 previous products that have had issues or not.

22 Q And concerning the beyond use date you mentioned
23 earlier, would you look into that further given only the
24 three documents that you have in front of you?

25 A I would want to know more information about how that

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1 was ascertained.

2 MS. PEIFFER: Thank you. No further questions.

3 THE COURT: All right.

4 May the Doctor be excused at this point, so to speak?

5 Ms. O'Shea?

6 MS. O'SHEA: Yes, Your Honor.

7 THE COURT: Ms. Peiffer?

8 MS. PEIFFER: Yes.

9 THE COURT: Dr. Ruble, that completes our
10 examination. Thank you so much for your valuable time.
11 We appreciate it very much, sir.

12 DR. RUBLE: Thank you, Your Honor. Good day, sir.

13 THE COURT: Yes, sir. You're excused, and free to
14 go.

15 **WITNESS STOOD ASIDE**

16 THE COURT: Next witness, Ms. Peiffer.

17 MS. PEIFFER: No further witnesses.

18 THE COURT: All right.

19 Ms. O'Shea, do you have evidence you want to put on
20 this afternoon?

21 MS. O'SHEA: We do, Your Honor. We have two
22 witnesses to testify by telephone.

23 If we would get Mr. Robinson. His phone number is
24 the one that begins with area code 75 --

25 THE COURT: Why don't you come up to the Clerk's desk

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1 to make sure Ms. Pizzini dials the right number, okay?

2 MS. O'SHEA: Of course.

3 THE COURT: All right. Thank you.

4 All right, Mr. Robinson, my name is Henry Hudson.

5 I'm the United States District Judge trying this case

6 today. Before Ms. O'Shea asks you questions, I'm going to

7 ask our Clerk of the Court, Ms. Pizzini, to administer the

8 oath.

9 Ms. Pizzini, if you would.

10 THE CLERK: You do solemnly swear that the testimony

11 which you are about to give, in this case, before this

12 Court, shall be the truth, the whole truth, and nothing

13 but the truth, so help you God?

14 MR. ROBINSON: I do.

15 THE COURT: You may inquire.

16 Whereupon, **Arnold D. Robinson**, having been

17 duly sworn in, testifies as follows:

18 **DIRECT EXAMINATION**

19 BY MS. O'SHEA:

20 Q Mr. Robinson, would you state your full name for the

21 Court, please.

22 A My name is Arnold David Robinson.

23 Q You're currently employed by the Virginia Department

24 of Corrections as its Chief Operating Officer.

25 A Yes. I am employed as the Chief of Corrections

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Operations for the Virginia Department of Corrections.

Q I misstated your title a little bit. I apologize.

What do you do as the Chief of Operations, briefly?

A I am responsible for all operational matters under the facilities within the Commonwealth, and all probation and parole districts in the Commonwealth of Virginia.

Q Do executions generally within the department fall within your auspices?

A Yes, they do.

Q I'm going to turn your attention now to a specific inmate by the name of Alfredo Prieto. Is he an inmate within the Virginia Department of Corrections?

A Yes. He is an inmate in the Virginia Department of Corrections.

Q And he is currently facing execution, is that correct?

A Yes, he is currently facing execution.

Q At some point, did you learn that Mr. Prieto's execution had been eminent such that he had almost exhausted his criminal habeas appeals, and a circuit court order setting a date of execution would be forthcoming soon?

A Yes. Somewhere around August I became aware of that.

Q At the time that you learned Mr. Prieto was nearing his execution date, did you have any concerns with respect

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1 to whether or not the Commonwealth of Virginia would be
2 able to execute him if we were to execute him by lethal
3 injection?

4 A Yes. I became concerned about that during August
5 when we found out of a possible date being established for
6 him. And at that time, I had a conversation between the
7 director and I.

8 Q Why were you concerned if he were to be executed
9 after September 30th?

10 A Because we knew that on October 1, 2015, that the
11 drug that we had, midazolam, would expire on September the
12 30th.

13 Q The midazolam that you referenced, that is the drug
14 that Virginia uses as the first step of its 3-drug
15 protocol?

16 A Yes. Midazolam would be the first drug that we would
17 use in the 3-drug protocol.

18 Q After that midazolam expired, did we have any other
19 drugs within the Virginia Department of Corrections that
20 we could use for the first step of that 3-drug protocol?

21 A Can you repeat that.

22 Q After that midazolam expired, did we have anything
23 else that we could use that was approved for use as the
24 first drug in Virginia's 3-drug protocol?

25 THE COURT: When you say --

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1 A No, we do not.

2 THE COURT: Excuse me, Mr. Robinson.

3 When you say "we," you're referring to the Virginia
4 Department of Corrections, correct?

5 MS. O'SHEA: I am. Yes. Thank you.

6 THE COURT: Okay.

7 Mr. Robinson, you may answer.

8 A No, we would not have any drug available for the
9 first drug in the 3-drug protocol after September 30,
10 2015.

11 BY MS. O'SHEA:

12 Q You referenced midazolam. Are there other substances
13 that have been approved by the Virginia Department of
14 Corrections to use?

15 A Yes. We have three drugs that's approved for the
16 first in the 3-drug protocol. One of those drugs is
17 thiopental, and pentobarbital is the second drug, and the
18 midazolam would be the third drug.

19 Q My understanding is that sodium thiopental was the
20 original drug in the 3-drug protocol, is that correct?

21 A That is correct.

22 Q And pentobarbital was subsequently approved. Do you
23 know when that was?

24 A It was, I believe, 2011 or '12. But I'm not 100%
25 sure on that.

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1 Q And then midazolam was the most recent approval. And
2 that would have been sometime in 2014?

3 A Yes. That's correct.

4 Q Turning now back to your concerns about Mr. Prieto's
5 execution. When you determined that the Virginia
6 Department of Corrections did not, or would not have, a
7 needed substance for his lethal injection, what did you
8 do?

9 A After a conversation between the director and I, I
10 contacted the Texas Department of Criminal Justice
11 service, a service which is in the Department of
12 Corrections in Texas, because I know that we had given
13 them in, I believe 2013, pentobarbital. And I was -- and
14 I knew that they were using that drug in their execution
15 protocol in Texas.

16 Q Who did you reach out to within the Texas Department
17 of Criminal Justice services?

18 A I contacted the individual in the same level within
19 the Department of Corrections in Texas that I am here in
20 Virginia. Their number two -- their number two person in
21 charge of the agency.

22 Q Is this someone that you are familiar with or had
23 known before?

24 A I have -- I've known him for several years through
25 contacts at national organizations that we go to in --

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1 part of training that we've been to together.

2 Q What did you discuss with the second in command at
3 the Virginia -- excuse me, the Texas Department of
4 Criminal Justice services?

5 A I explained to him our situation. And if it would be
6 possible that we could obtain from them the pentobarbital
7 that they're using in the Department of Corrections in
8 Texas for executions.

9 Q And ultimately, did Texas agree to provide Virginia
10 with pentobarbital?

11 A Yes, they did.

12 Q During the course of your conversations with the
13 Texas official, were there any discussions regarding the
14 source or composition of the pentobarbital?

15 A In the conversations with him, he advised that -
16 MR. LEE: Objection, Your Honor.

17 A - the drug was a compounded drug.

18 THE COURT: Mr. Robinson, hold off, sir.

19 MR. ROBINSON: Yes, sir.

20 THE COURT: Mr. Lee.

21 MR. LEE: That's hearsay, Your Honor. He can't
22 testify to representations.

23 MR. ROBINSON: I can barely hear.

24 THE COURT: Hold on. Hold on, Mr. Robinson. Just
25 one second. We'll be right back to you, sir.

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1 Mr. Lee, I believe what he was testifying to is why
2 he took a certain act, and not for the truth of the
3 matter. If that is the way the question is being asked,
4 I'll overrule it; otherwise, I'll sustain the objection.

5 MR. LEE: Your Honor, I heard him begin to say this
6 person said, and then that's when I objected.

7 THE COURT: All right.

8 Why don't you rephrase the question. I'll sustain
9 Mr. Lee's objection. Why don't your rephrase the question
10 so that it's foundational and not offered for the truth of
11 the matter, okay?

12 MS. O'SHEA: Absolutely, Judge.

13 THE COURT: Go ahead.

14 BY MS. O'SHEA:

15 Q Mr. Robinson, did you inquire into the source or
16 composition of the pentobarbital that Texas was offering
17 to provide to Virginia?

18 A Yes. In conversation with the number two person in
19 Texas, I --

20 THE COURT: Mr. Robinson, I think she only asked for
21 a yes or no answer.

22 A Yes.

23 THE COURT: Yes. Next question.

24 BY MS. O'SHEA:

25 Q What did you ask?

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1 A In the conversation, he advised that --

2 MR. LEE: Objection, Your Honor.

3 THE COURT: Hold on, Mr. Robinson.

4 Mr. Lee, in the interest of shortness of life, I'm
5 going to let it in, and we can argue whatever value it
6 has. Let's just proceed with it.

7 Go ahead, Mr. Robinson.

8 A He advised me that the pentobarbital that they use in
9 the executions in Texas -- advised me that it has been
10 compounded in Texas. And that he had a certificate that
11 verified the validity of the drug, and that they had used
12 it in the previous executions in Texas.

13 THE COURT: I'm only going to accept that as a
14 preface of how you received the drug, not for the truth of
15 the matter, okay?

16 MS. O'SHEA: Absolutely, Judge.

17 THE COURT: All right. Go right ahead. Next
18 question.

19 BY MS. O'SHEA:

20 Q Based on the representations from the Texas official,
21 did Virginia at that time decide that they wanted to
22 acquire the pentobarbital from Texas?

23 A Yes, we did.

24 Q Who -- or how did you decide to go and get the
25 pentobarbital from Texas? How did you decide for it to be

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1 delivered here?

2 A We decided that we would send two individuals to
3 Texas via car to pick up the drugs and return them to
4 Virginia. Similar to how Texas picked up the drugs in
5 2013 from us.

6 Q Who did you select to go to Texas?

7 A I selected Carlos Hernandez, who is the individual in
8 Virginia who has carried the drugs between our pharmacy in
9 Greensville for many years, and had received training from
10 our pharmacist on how to transport those drugs. So just
11 pretty much on-the-job training for the last 12 years.

12 Q So, to your knowledge, Mr. Hernandez when to Texas
13 and returned with the pentobarbital, is that correct?

14 A That is correct.

15 Q Do you have personal knowledge of what Mr. Hernandez
16 did with the pentobarbital upon his return to Virginia?

17 A Upon his return to Virginia -- he came back on
18 Thursday. I'm not familiar with the specific date. He
19 arrived, our pharmacist met him. We secured it that night
20 in the pharmacy here at our headquarters at the Virginia
21 Department of Corrections.

22 Q So when you say he met with "*our pharmacist*," you're
23 speaking of the pharmacist for the Virginia Department of
24 Corrections?

25 A Excuse me?

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1 Q When you said "*our pharmacist*," did you mean the
2 pharmacist for the Virginia Department of Corrections?

3 A Yes. The pharmacist for the Virginia Department of
4 Corrections.

5 Q What happened to the pentobarbital after it was
6 secured at the headquarters?

7 A Once it was secured at the headquarters, it was
8 secured in their pharmacy area behind lock and key. That
9 room has one door that enters the room, plus it is alarmed
10 through an alarm company, and is monitored by a security
11 guard at our front desk. It also has a motion monitor in
12 the area.

13 It was secured at that time, and remained there until
14 picked up by Greenville Correctional Center employees
15 that have been trained to carry that drug back to
16 Greenville.

17 Q During the course of your conversations with Texas,
18 did you write anything down in the forms of
19 correspondence, or memorandum, or contracts, or anything
20 along those lines?

21 A No, I did not.

22 Q To your knowledge, did anybody else with the Virginia
23 Department of Corrections write anything down?

24 A Not to my knowledge. No.

25 Q Why not?

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1 A The conversation that I had --

2 THE COURT: Hold on. Hold on.

3 MR. ROBINSON: All right.

4 THE COURT: I think the objection has got to be
5 sustained to that. He's going to testify as to what
6 someone explained to him in the State of Texas. It is
7 hearsay. Inadmissible. Objection is sustained.

8 Next question.

9 MS. O'SHEA: Yes, Your Honor.

10 BY MS. O'SHEA:

11 Q Why did you not write anything down, Mr. Robinson?

12 A Because after talking with my counterpart in Texas, I
13 was confident that what he was sending me was
14 pentobarbital. And I had no need to because of our
15 professional relationship.

16 Q During the course of your conversation with Texas,
17 you learned that the pentobarbital was compounded, I
18 believe you testified to that earlier, is that correct?

19 A That is correct.

20 Q To your knowledge, has compounded pentobarbital been
21 used in an execution in Virginia?

22 A Not to my knowledge. No.

23 Q The fact that this was compounded as opposed to
24 manufactured pentobarbital, did that raise any concerns
25 with you?

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1 A No, it did not.

2 Q Why not?

3 A Because I understand from Texas that it's been used
4 24 times, 15 this year. And also, I was provided with --
5 the Attorney General's office was provided with a
6 certificate showing the certification that it was
7 pentobarbital.

8 Q Thank you, Mr. Robinson. I'm going to ask you just a
9 couple more questions now, and these are specific to
10 Virginia's execution protocol.

11 You testified earlier that pentobarbital is the first
12 drug that is administered in the Virginia 3-drug protocol,
13 is that correct?

14 A That is correct.

15 Q And what is your understanding of the reason that
16 this first drug is administered? What is it supposed to
17 do?

18 A That drug sedates the individual and puts them in an
19 unconscious state.

20 Q After the first drug is administered --
21 intravenously, correct? It's administered intravenously?

22 A That's correct.

23 Q After the first drug is administered according to
24 Virginia's execution protocol, is anything done within the
25 execution chamber to ascertain whether or not the sedative

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1 has taken effect?

2 A Yes, there is.

3 Q What is that?

4 A After the -- after the first drug is administered,
5 there is a saline solution that is also pushed behind that
6 drug. In approximately two minutes, then we have what we
7 call a noxious test that we test to determine the
8 consciousness of the individual. And that is by
9 pitching -- that is by pinching the individual's right or
10 left foot depending on the individual who does that. But
11 we're trained to do that.

12 Q So there's an individual in the execution chamber who
13 is trained to pinch the foot of the inmate to determine
14 whether or not the first drug has taken effect?

15 A That's correct.

16 Q According to Virginia's execution protocol, if the
17 sedative has not taken effect, what happens next?

18 A Then we will repeat that process.

19 MS. O'SHEA: If I could have just a second, Your
20 Honor.

21 THE COURT: Yes, ma'am.

22 MS. O'SHEA: I have no other questions at this time,
23 Mr. Robinson, but Mr. Prieto's counsel likely do. Thank
24 you.

25 THE COURT: Mr. Lee.

CROSS-EXAMINATION

BY MR. LEE:

Q Chief Robinson, this is Rob Lee.

A Yes, sir.

Q Thank you for your testimony today. We'll just start with something that you had just said. You said you would repeat the process. What is the process that you would repeat?

A He would re-administer a second dose of the pentobarbital.

Q Okay. And correct me if I'm wrong, but I heard your testimony before to be that the decision of the Department of Corrections to use compounded pentobarbital in executions was based on your telephone conversation with your counterpart with the Texas Department of Criminal Justice, and the provision of a laboratory report that is before this Court as Exhibit 1?

A Can you ask that question again, Mr. Lee?

Q Yes. I understood your testimony before to be that the decision to use compounded pentobarbital from the Texas Department of Corrections was based on your telephone conversation with your counterpart in Texas, and the lab report that they provided, which is before this Court as Exhibit 1?

THE COURT: I don't know that he could identify

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1 Exhibit 1. I doubt he's seen that.

2 MR. LEE: Well, okay.

3 BY MR. LEE:

4 Q You said that there was -- that the person you spoke
5 with was going to provide a lab report, a certificate.

6 A The person advised me that if there was questions
7 concerning the validity of the pentobarbital, that they
8 would provide certification of such. And we asked for
9 that. And that was sent to the Attorney General's office.

10 MR. LEE: And, Ms. O'Shea, will you acknowledge that
11 that's Exhibit 1, that document?

12 MS. O'SHEA: Actually, I believe the document is
13 Exhibit Number 3.

14 MR. LEE: Okay. I'm sorry. Number 3. And Exhibit 1
15 was the photograph.

16 BY MR. LEE:

17 Q Thank you, Mr. Robinson.

18 So nothing else was done, is that correct?

19 A When you say "*nothing else was done*," from the
20 standpoint of our agency doing anything with that?

21 Q No. I'm sorry. Let me be more precise. There was
22 no additional independent research that went into making
23 this decision?

24 A Independent research. No, sir.

25 Q Okay. There was no consultation with experts?

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1 A No, sir.

2 THE COURT: You're talking about to determine the
3 efficacy of the compound he received?

4 MR. LEE: Yes. And the decision.

5 THE COURT: And the decision. Okay. Go ahead.

6 BY MR. LEE:

7 Q Mr. Robinson, can you tell us the difference between
8 compounded pentobarbital, and F.D.A. approved
9 pentobarbital?

10 A No, I cannot.

11 Q Are you aware of the difference between Texas'
12 execution protocol and Virginia's execution protocol?

13 A I'm familiar with the Texas protocol. Correct.

14 Q Can you just describe it, briefly.

15 A They just use the one drug, pentobarbital.

16 Q And are you aware of the approximate length of time
17 in Texas executions for the 1-drug pentobarbital and
18 protocol?

19 A No. I'm not familiar with the length of time. I
20 know that in conversation with my counterpart, that's the
21 drug that they use in Texas for executions. And it's a
22 single drug protocol. And I know that he advised that
23 they had used it 24 times, and that it was a compounded
24 drug.

25 MR. LEE: I don't have anymore question.

REDIRECT EXAMINATION OF ARNOLD ROBINSON

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1 THE COURT: Any redirect, Ms. O'Shea?

2 MS. O'SHEA: Briefly.

3 REDIRECT EXAMINATION

4 BY MS. O'SHEA:

5 Q Mr. Robinson, do you know whether any other
6 jurisdictions use compounded pentobarbital as a part of
7 their execution protocol?

8 A No, I do not know other than Texas.

9 Q If when you were speaking with Texas, if they had
10 been unable to provide you with assurances regarding the
11 pentobarbital, the fact that it had been tested, that it
12 was what it claimed to be, would you have accepted it from
13 Texas anyways?

14 A No, we would not have.

15 MS. O'SHEA: I have no further questions.

16 THE COURT: May Mr. Robinson be excused?

17 MR. LEE: Can I have a brief follow-up? Never mind,
18 Your Honor.

19 THE COURT: All right.

20 Mr. Robinson, thank you very much for your testimony
21 today. That completes the examination. We thank you for
22 your time, sir.

23 MR. ROBINSON: Thank you, Your Honor.

24 THE COURT: Yes, sir. Thank you.

25 WITNESS STOOD ASIDE

DIRECT EXAMINATION OF CARLOS HERNANDEZ

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MS. O'SHEA: I have one other witness.

THE COURT: Yes, ma'am. Who is your next witness?

MS. O'SHEA: His name is Carlos Hernandez.

THE COURT: Carlos Hernandez.

Mr. Hernandez, my name is Henry Hudson. I'm the
United States District Judge trying this case today.

MR. HERNANDEZ: Yes, sir.

THE COURT: And before you're questioned by
Ms. O'Shea, I'm going to have our Clerk of the Court
administer the oath to you, okay, sir?

MR. HERNANDEZ: Yes.

THE COURT: Go right ahead, Ms. Pizzini.

THE CLERK: You do solemnly swear that the answers to
the questions which you are about to be asked shall be the
truth, the whole truth, and nothing but the truth, so help
you God?

MR. HERNANDEZ: Yes, ma'am.

THE COURT: All right, Ms. O'Shea. Go right ahead.

MS. O'SHEA: Thank you.

Whereupon, **Carlos A. Hernandez**, having been
duly sworn in, testifies as follows:

DIRECT EXAMINATION

BY MS. O'SHEA:

Q Sir, would you state your full name for the Court,
please.

DIRECT EXAMINATION OF CARLOS HERNANDEZ

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1 A Carlos Alberto Hernandez.

2 Q You're currently employed be the Virginia Department
3 of Corrections?

4 A Yes, ma'am.

5 Q In what capacity?

6 A I am the Administrator of Special Operations.

7 Q How long have you been with the department?

8 A Twenty-eight years, ma'am.

9 Q It is my understanding that you have been trained
10 within the department to handle drugs or pharmaceutical
11 substances, is that correct?

12 A It was on-the-job training. Yes, ma'am.

13 Q As a part of your duties, do you transport drugs that
14 are to be used in an execution?

15 A Yes, ma'am.

16 Q How many years have you been doing that?

17 A Twelve years, ma'am.

18 Q At some point in August of 2015, were you asked to go
19 to Texas to secure a supply of lethal injection drugs?

20 A Yes, ma'am.

21 Q How -- how did this come to your attention? How were
22 you asked to go?

23 A I received a phone call from my supervisor. And I
24 was informed that I would be taking a trip to Texas.

25 Q Did you in fact go to Texas?

DIRECT EXAMINATION OF CARLOS HERNANDEZ

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1 A Yes, ma'am.

2 Q Where specifically did you go?

3 A Huntsville.

4 Q Huntsville, Texas?

5 A Yes, ma'am.

6 Q What did you do when you got there?

7 A Picked up three vials.

8 Q Where did you get them from?

9 A The facility. The Huntsville facility.

10 Q Is that a Texas --

11 A A correctional facility.

12 Q A Texas correctional facility in Huntsville?

13 A Yes, ma'am.

14 Q When you arrived at the facility, who, if anyone, did

15 you interact with?

16 A It was one of the administrative staff.

17 Q One of the administrative staff. And you testified a

18 second ago that three vials of drugs came into your

19 possession?

20 A Yes, ma'am.

21 THE COURT: Hold on just one second.

22 Ms. Peiffer, I've read over all the pleadings. Is

23 this really an issue in this, what Mr. Hernandez did?

24 MS. PEIFFER: Your Honor, I believe the issue is

25 about the conditions of the substance, this very fragile,

1 delicate substance.

2 THE COURT: Okay. I'll go ahead and go through it.
3 That's fine. I just didn't detect it in your brief, but
4 go ahead.

5 BY MS. O'SHEA:

6 Q Three vials of a substance labeled as pentobarbital
7 were brought into your possession, is that correct?

8 A Yes, ma'am.

9 Q Did you receive instructions, or ask for
10 instructions, with regard to how to handle this particular
11 substance?

12 A Yes, ma'am.

13 Q From whom?

14 A The person that issued me the drugs.

15 Q What were you told with respect to how to handle or
16 store the pentobarbital?

17 A I was told to keep them at room between 60 and
18 80 degrees, ma'am.

19 Q And specifically, how were the drugs packaged when
20 they were given to you?

21 A They were in three vials that were in a cardboard box
22 with bubble wrap on the bottom of the box.

23 Q Three vials inside a box, is that what you just said?

24 A Yes, ma'am.

25 Q What type of box was it?

DIRECT EXAMINATION OF CARLOS HERNANDEZ

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1 A It was a cardboard box.

2 Q Cardboard box. Did it have a lid?

3 A Yes, ma'am.

4 Q Okay. So could sunlight penetrate into the cardboard

5 box?

6 A No, ma'am.

7 Q At the time that you picked up the three vials of

8 pentobarbital, did you execute any paperwork?

9 A Yes.

10 Q What did you execute?

11 A I believe it was a DEA Form 222.

12 Q A DEA Form 222?

13 A Yes, ma'am.

14 Q To your knowledge, what is the purpose of executing

15 that form?

16 A I'm sorry?

17 Q What is the purpose of filling out that form?

18 A Well, to make sure that there's a chain of custody.

19 Q So to legally transfer custody from Texas to

20 Virginia?

21 A Yes, ma'am.

22 Q After you picked up the three vials of pentobarbital

23 in the box from the Huntsville facility, what did you do

24 with them?

25 A There were placed inside an ammo box, a plastic ammo

DIRECT EXAMINATION OF CARLOS HERNANDEZ

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1 box, and locked.

2 Q What is a plastic ammo box? Would you describe it,
3 please.

4 A It's a plastic ammo -- a plastic box with a hinged
5 lid that is locked.

6 Q After you placed it in the box, what did you do with
7 it next?

8 A Kept it in my possession.

9 Q When you say kept it in your possession, where did
10 you put it?

11 A Well, from the facility it was in the vehicle with
12 me. When I got to the hotel room, it went up to the hotel
13 room with me. From there, it came back to the Virginia
14 Department of Corrections pharmacy.

15 Q And when you brought it back to Virginia, it was in
16 your car?

17 A Yes, ma'am.

18 Q Which part of your car?

19 A The back seat.

20 Q As you were driving the pentobarbital back to
21 Virginia, what, if anything, did you do to ensure that it
22 had not gotten too hot or too cold?

23 A I kept feeling it with the back of my hand.

24 Q What did you do with the pentobarbital when you
25 arrived in Virginia?

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1 A Took it up to the pharmacist. It was about 9:00
2 a.m. -- 9:00 p.m. Took it to the pharmacist. He opened
3 the box, and accounted for the three vials.

4 MS. O'SHEA: All right. Thank you, Mr. Hernandez. I
5 don't have any other questions at this time, but
6 Mr. Prieto's counsel might.

7 THE COURT: All right.

8 Mr. Lee.

9 CROSS-EXAMINATION

10 BY MR. LEE:

11 Q Mr. Hernandez, my name is Rob Lee. I'm going to ask
12 you a few questions about what you were just talking about
13 with Ms. O'Shea.

14 A Yes, sir.

15 Q You say that you had on-the-job training in the
16 transport and storage of chemicals used in executions, is
17 that correct?

18 A Yes, sir.

19 Q Can you briefly describe what on-the-job training
20 means, just briefly?

21 A I was -- I was taken to -- from the pharmacy down to
22 our facility where we conduct our executions. The box is
23 unlocked. Everything is accounted for at the pharmacy.
24 The box is then locked.

25 We take it down to the facility. It is opened by the

CROSS-EXAMINATION OF CARLOS HERNANDEZ

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1 facility. I do not have a key. We recount it. The form
2 is completed. I get a copy and they keep a copy.

3 Q Okay. Thank you.

4 Now, you testified that you traveled to Texas in
5 August of 2015?

6 A Yes, sir.

7 Q Did you travel as a D.O.C. employee?

8 A Yes, sir.

9 Q And it sounds like you drove. Am I correct?

10 A That's correct.

11 Q Did you drive a D.O.C. vehicle?

12 A Yes, sir.

13 Q Is that -- did you document checking out the vehicle
14 at all?

15 A No. It's a vehicle that is assigned to me, sir.

16 Q I'm sorry. I couldn't hear you.

17 THE COURT: He said it was a vehicle assigned to him.

18 MR. LEE: Okay.

19 BY MR. LEE:

20 Q Now, you said that you essentially maintained a chain
21 of custody of the bottles?

22 A That is correct.

23 Q And how did you do that?

24 A It never left my possession.

25 Q So who did you receive the chemicals from?

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1 A Again, it was one of the administrative officials
2 from Texas.

3 Q But you don't know the person's name?

4 A No, sir.

5 Q You didn't record the person's name?

6 A I have it in my office. I'm not at the office right
7 now, sir.

8 Q I'm sorry. I'm not trying to confront you about
9 that, Mr. Hernandez.

10 A That's fine.

11 Q I just wanted to know whether you had any -- you
12 documented that chain of custody, or it's just in your
13 head?

14 A I have the gentleman's name in my office. I have his
15 business card.

16 Q When he transferred custody to you though, was there
17 any document created?

18 A Yes. The DEA 222.

19 Q And his name is on that?

20 A Yes, sir.

21 Q Okay. Did you document in any way transporting the
22 materials?

23 A No, sir.

24 Q And you said that you then turned them over to
25 someone else?

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1 A Yes, sir. The pharmacist.

2 Q And is there any record of that?

3 A Yes.

4 Q And can you describe that record?

5 A It's on the same DEA 222.

6 Q It has a date of the -- the date and time of
7 transfer?

8 A Yes.

9 Q You also said that when you received the drugs, you
10 were instructed to maintain them at room temperature?

11 A Yes.

12 Q And you've stored the drugs now since obtaining them
13 at room temperature as well, is that correct?

14 A From the time I received them until the time I
15 delivered them. Yes, sir.

16 Q And when you delivered them -- I'm sorry, but you
17 said you were trained in the transport and storage of
18 drugs. Are they stored at room temperature as well?

19 A Not stored, sir. I'm transporting them.

20 Q So in terms of chain of custody, you don't know how
21 the drugs were stored or maintained after you -- before
22 you got them or after you released them?

23 A I do not.

24 Q When you have transported drugs before for the
25 department, have they been received -- have you also been

CROSS-EXAMINATION OF CARLOS HERNANDEZ

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1 instructed to maintain them at room temperature?

2 A They have been packaged at the pharmacy. So I have
3 not been instructed to keep them at room temperature.

4 Normally, my trip is no longer than about an hour.

5 MR. LEE: Can I have one second, Your Honor?

6 THE COURT: Yes, sir.

7 MR. LEE: That's it, Your Honor. Thank you.

8 THE COURT: Okay. Yes, sir.

9 Ms. O'Shea.

10 MS. O'SHEA: If I could just -- the DEA Form 222 that
11 we've been discussing is the document previously admitted
12 as Plaintiff's Exhibit 2, is that correct, Mr. Lee?

13 MR. LEE: Yes.

14 MS. O'SHEA: Okay. I just wanted to make that clear
15 on the record that the document we discussed is
16 Plaintiff's Exhibit 2.

17 THE COURT: Appreciate your clarification.

18 MS. O'SHEA: Thank you.

19 THE COURT: Any redirect?

20 MS. O'SHEA: No, sir.

21 THE COURT: All right.

22 Mr. Hernandez, that completes the examination today.
23 Thank you very, very much for your time. We appreciate
24 your testimony.

25 MR. HERNANDEZ: Yes, sir.

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1 THE COURT: You're excused and free to go.

2 MR. HERNANDEZ: Thank you, sir.

3 WITNESS STOOD ASIDE

4 THE COURT: All right. I'll hear final comments from
5 each side.

6 You're the movant. Go right ahead, Ms. Peiffer.

7 MS. PEIFFER: Thank you, Your Honor. I'll try to
8 keep this brief.

9 I think that the standard here that Mr. Prieto shows
10 a likelihood of success on the merits that he can show a
11 substantial risk of harm if the Department of Corrections
12 proceeds with his execution using this compounded
13 pentobarbital without really any due diligence or research
14 or sufficient investigation, that he would suffer cruel
15 and unusual punishment that would violate the Eighth
16 Amendment.

17 There are a couple of points --

18 THE COURT: The possibility is not the standard
19 though. I think you're going to have to show that there's
20 a substantial risk of injury, which is more than a
21 speculative possibility in a high-abstract zone. This is
22 very, very specific. So point to that as you argue your
23 case, okay? Make sure you identify that for me.

24 MS. PEIFFER: Yes, sir.

25 THE COURT: Okay. Go ahead.

1 MS. PEIFFER: So there are a couple of points that I
2 want to touch on that support the argument that there is a
3 likelihood of success on the merits that he has shown a
4 substantial risk of harm.

5 First of all, the protocol in Virginia is unique in
6 terms of using a 3-drug protocol, trying to use a
7 compounded pentobarbital as the first drug. And that is
8 why it is distinguished from Texas. I addressed this
9 earlier. But drugs that are sufficient for use in Texas,
10 or that Texas assures might be sufficient for an execution
11 there, don't automatically translate to use in Virginia.
12 Virginia has --

13 THE COURT: Well, I understand that. But in Texas,
14 they use strictly pentobarbital, do they not?

15 MS. PEIFFER: That is correct. To my understanding.

16 THE COURT: So if the compound from Texas is
17 high-risk, wouldn't the fact that it's been used on 24
18 other occasions, 15 times this year, wouldn't that be
19 probative? The same drug.

20 MS. PEIFFER: I'm actually glad that you brought that
21 up, Your Honor. That was a later point in my argument.

22 THE COURT: All right.

23 MS. PEIFFER: And I think that statement demonstrates
24 that the Department of Corrections doesn't understand
25 compounded pentobarbital. It doesn't understand how it's

1 different from manufactured pentobarbital.

2 The statement that it was used over the past two
3 years in 24 executions -- for at least 24 executions,
4 shows a misunderstanding that compounded pentobarbital is
5 not one category. It is variable, and it depends on the
6 specific batches.

7 So as you heard from Dr. Ruble, every batch of
8 compounded pentobarbital is different. And then the
9 product changes based on the conditions in which it's
10 kept, the conditions in which it's stored, the things that
11 it's exposed to. So the claim that Texas has been using
12 this chemical for the past two years is incorrect. This
13 batch of pentobarbital, according to the documents we
14 received, was only made in April of 2015.

15 THE COURT: Well, I don't know that he testified that
16 it was exactly the same batch. The evidence is unclear on
17 that. But he did say it was compounded pentobarbital.

18 MS. PEIFFER: That's correct.

19 THE COURT: Okay.

20 MS. PEIFFER: And the point that I'm trying to make,
21 and I apologize for not being clear -

22 THE COURT: That's okay.

23 MS. PEIFFER: - is that compounded pentobarbital is
24 not the same from batch to batch. There is a variability.
25 And that's part of the reason that testing is so

1 significant in the compounding field because every batch
2 is different. There's a reason that it's not the same as
3 manufactured pentobarbital, which has different -- can be
4 kept in different conditions, it is much more stable, and
5 there's much less concern because it's made in
6 professional ways, and regulated by the F.D.A.

7 So lumping all compounded pentobarbital into one
8 category is just not sufficient. And that's why, in this
9 particular case with this particular chemical, it's so
10 significant that due diligence and investigation be done
11 into the product.

12 You've heard Mr. Robinson's testimony that basically
13 he said after talking with his counterpart, that he felt
14 no need to look further due to a professional
15 relationship. He felt no need to investigate these
16 materials that were going to be used to put someone to
17 death.

18 And when listening to Dr. Ruble's testimony --

19 THE COURT: I don't mean to interrupt you.

20 But in fact he did. He made sure that there was a
21 lab test that said it was 94.5% pentobarbital.

22 MS. PEIFFER: There was a lab test. That's correct.
23 I think there's some issues with the lab test that he did
24 not address, and was not able to address. As Dr. Ruble
25 testified, the lab test says nothing about sterility.

1 Sterility testing is required, particularly if they're
2 going to attempt to assign an extended beyond use date.
3 That's absolutely required.

4 So we're left with a lot of questions about whether
5 this -- the proper testing wasn't done, whether Virginia
6 didn't inquire into the proper testing. But they should
7 have known if they had done their research and done their
8 investigation about this chemical if they're going to try
9 to use this as part of the 3-drug protocol. They should
10 have come to understand enough that investigation would
11 need to be done. That it's unusual to have a beyond use
12 date of one year.

13 And to be able to set that beyond use date, there has
14 to be extensive sterility testing. And none of the
15 documentation that we received shows any indication that
16 there was any sterility testing, let alone, I think, that
17 would allow for a one year use by date.

18 As we heard from Dr. Ruble, usually without that
19 sterility testing, if the material were refrigerated, the
20 beyond use date would be three days. That is 72 hours.
21 And in this case, we're going on six months after it was
22 made.

23 And we have heard nothing about the conditions of how
24 it was made and why sterility testing would justify this
25 excessive beyond use date. So that in and of itself, I

1 think, raises substantial questions. And I think they
2 should have done some investigation, and looked into this
3 to see if this mixture really is sufficient to use as
4 compounded pentobarbital as the first chemical of the
5 lethal injection protocol.

6 I think there are other issues with the testing which
7 we heard about today. You mentioned potency earlier. And
8 there is a potency test in that material. The potency is
9 at the low end of the range right after it's manufactured.
10 We don't know what the potency is today. The potency in
11 April of 2015 could have degraded substantially by this
12 point in October. And one of the reasons that's possible
13 is because, you know, a beyond use date typically would be
14 much shorter than the five to six month period.

15 We've heard a little bit about the conditions of
16 storage. Mr. Robinson's testimony seemed to focus
17 primarily on security. We did hear that when it was
18 transported, it was kept, according to the testimony, in a
19 60- to 80-degree temperature range, which according to
20 Dr. Ruble's expert testimony, is not the way that
21 compounded pentobarbital should be kept. He testified
22 that in order to extend the life and extend the potency
23 and to make sure it doesn't degrade, it should be
24 refrigerated. And 60 to 80 degrees is not equivalent to
25 cold temperature or refrigeration. So that also raises

1 questions.

2 And again, we didn't have access to that information
3 before, so it is not in the pleadings. We had repeatedly
4 asked for information about how things were transported,
5 and the conditions in which they were transported and
6 stored, and this hearing today to is the first time we've
7 received that information.

8 Sterility -- so potency, sterility, both of those
9 things could cause issues with the drug. And Mr. Prieto
10 has shown that because it's so significant in the 3-drug
11 protocol, that for the first drug to do what it's supposed
12 to do, that it is to render him unconscious and insensate,
13 that there is a substantial risk. Drugs that haven't been
14 properly sterility tested can cause some kind of reaction.
15 They may not work.

16 As you mentioned earlier, in Texas this could also be
17 the case. It's unclear because we have not been able to
18 receive the information about whether any of this batch
19 has been used in any Texas executions. But what we do
20 know is that it is absolutely clear from all of the
21 evidence we've been able to receive, and heard today, that
22 the Department of Corrections doesn't really understand
23 the precautions that need to be taken with a very fragile
24 substance like compounded pentobarbital. And they haven't
25 done their investigation. They haven't looked into this.

1 And that raises serious concerns that there will be a
2 substantial risk of harm to Mr. Prieto with the chemical
3 kept in warm temperatures which could have well degraded
4 well below the 94.6% potency rate, and therefore not be
5 able to operate as it's supposed to render him
6 unconscious.

7 And just to note in terms of that, you know,
8 Mr. Prieto, there was some discussion earlier about
9 execution of remedies. He has tried multiple times to
10 obtain this information. The purpose of the exhaustion
11 requirement is that the Department of Corrections would
12 have an opportunity to address the information and the
13 situation before it has to come to a court. And that is
14 certainly what Mr. Prieto tried to do.

15 He tried to, at the earliest opportunity that he was
16 able to, obtain this information. He started trying to
17 get more. Because as we mentioned earlier, we're not
18 saying that the Department of Corrections cannot --

19 THE COURT: I understand this is an emergency motion.

20 MS. PEIFFER: Okay.

21 THE COURT: I certainly understand that.

22 MS. PEIFFER: Okay. When then I will forgo anymore
23 discussion of exhaustion.

24 But just to mention briefly the feasible alternative,
25 because that is something that has to be shown in the

1 Eighth Amendment claim. Mr. Prieto has shown a feasible
2 alternative. He's not saying that compounded
3 pentobarbital can never be used. All he's saying is that
4 it has to properly investigated, and that the
5 responsibility of using compounded pentobarbital has to be
6 taken --

7 THE COURT: What source would you recommend that the
8 Virginia Department of Corrections use for that? Do you
9 have one available?

10 MS. PEIFFER: Do I have a source --

11 THE COURT: Yes. For the pentobarbital.

12 MS. PEIFFER: Well, it could be that the source
13 they've already used is acceptable. We just don't know
14 that without the proper testing and the proper
15 investigation. And it seems clear from the testimony
16 today that they did not pursue that.

17 There are a number of laboratories making compounded
18 pentobarbital. And with all due respect, I don't think
19 the standard is that I have to provide a laboratory today
20 that they can turn to. But we do know that many states
21 use compounded pentobarbital. They obtained compounded
22 pentobarbital.

23 THE COURT: Okay.

24 MS. PEIFFER: But because of the secrecy laws and the
25 fact that we're not allowed to know what laboratories are

1 making the pentobarbital, I can't list off laboratories.
2 But that's certainly one of the factors in understanding
3 the quality and the potency and the stability of the drug.
4 And that's why it's so important to obtain this
5 information instead of blindly trusting that it will do
6 what it's supposed to do.

7 And going back to just the point of -- because I
8 think the point about when you're able to obtain this
9 information also goes to the balance of equity.

10 Mr. Prieto has tried to obtain this information. He's
11 tried to propose a feasible alternative. And the
12 information just keeps coming out piecemeal.

13 First, there was this FOIA response. I have only the
14 photograph of the bottles and one DEA form. And FOIA
15 requests have been made continuously to the Virginia
16 Department of Corrections. And the first time any of this
17 information came to light was in September. And that
18 seemed, based on the requirements of FOIA, that that was
19 all that was out there.

20 Then when Mr. Prieto told counsel for the Virginia
21 Department of Corrections that he was considering filing a
22 law suit because there was no other way to get the
23 information, the Virginia Department of Corrections
24 responded to the letter three hours later, and provided
25 very minimal information that was vague and conclusory.

1 It didn't really do anything other than raise further
2 concerns that the Department of Corrections were not
3 taking their responsibility to investigate this seriously,
4 including misunderstanding -- I think Your Honor mentioned
5 earlier about thinking that compounded pentobarbital is
6 all the same, instead of recognizing that it's very
7 variable, and depends on the way it is made and the way it
8 is stored and what happens to those mixtures.

9 And then it was very surprising after the lawsuit was
10 filed, and the motion to dismiss was filed late yesterday
11 afternoon, and that's the first time that the lab testing
12 came to light. Until this point, we had no knowledge of
13 what lab testing was done. And at that point, as I
14 mentioned, the lab testing still doesn't show that the
15 necessary testing has been done to show that this drug can
16 be used, and that it would not cause a substantial risk of
17 serious pain to Mr. Prieto in violation of the Eighth
18 Amendment.

19 Do you have any further questions, Your Honor?

20 THE COURT: Not right now. No, ma'am. Thank you.
21 Very nice job.

22 MR. LEE: Your Honor, can I make one short comment?

23 THE COURT: No. We don't do that. You know that,
24 Mr. Lee. You can give the rebuttal argument if you wish.
25 But, no, I'm not going to allow you to alternate final

1 arguments.

2 Ms. O'Shea.

3 MS. O'SHEA: Yes, Your Honor.

4 Just to correct, or comment, on a couple of things
5 that just came up in closing arguments from Mr. Prieto's
6 counsel. Virginia's 3-drug protocol, actually, is not
7 unique. We will not be the first jurisdiction to use
8 compounded pentobarbital as the first substance in a
9 3-drug execution. So I just wanted to bring that to the
10 Court's attention.

11 THE COURT: That's fine. I accept your
12 representation, but I have no evidence of that before me.
13 So I accept your representation for what it's worth, but
14 it doesn't constitute evidence. So go ahead.

15 MS. O'SHEA: It does not.

16 Texas does have a different protocol than we do.
17 They use the pentobarbital as their lethal agent. It is
18 what they administer to kill. And they have used this in
19 24 executions. They have been storing it at 60 to
20 80 degrees. That's the instructions that Texas gave us on
21 how they store their compounded pentobarbital from their
22 pharmacy where they got it from.

23 And they have had no issues with respect to utilizing
24 this particular drug. The Virginia Department of
25 Corrections was entitled to rely upon representations from

1 Texas officials as to how to store their pentobarbital
2 that they have made and they have been using in executions
3 for the past two years.

4 With regard to the beyond use date that has been
5 bought up, the 1-year date on the bottle, there's no
6 evidence of it one way or the other. But I would note
7 that a 1-year beyond use date tends to indicate that the
8 substance was actually well sterilized and well preserved,
9 or it wouldn't have been given a date that long.

10 Moreover, their own expert testified that a 1-year
11 date was not out of the realm of possibility. That he
12 usually saw three to six months, but that up to 1-year was
13 certainly feasible. So that extended use by date was only
14 a --

15 THE COURT: He said that was on the outer end of time
16 period of which you can use it.

17 MS. O'SHEA: On the outer end. Yes. But that's
18 still within limits, correct? Yes.

19 With regard to the legal standing, Your Honor is very
20 familiar with it, so I'm not going to harp on it too much,
21 but --

22 THE COURT: This is not the first preliminary
23 injunction I've handled. I assure you.

24 MS. O'SHEA: I am certain it is not, Your Honor.

25 THE COURT: Okay.

1 MS. O'SHEA: *"Sure or very likely to cause serious*
2 *illness or needless suffering."* There has been no
3 evidence here today. Nothing alleged other than sheer
4 speculation that if the pentobarbital was not made
5 correctly, if it wasn't stored correctly, if it wasn't
6 brought to Richmond correctly, maybe perhaps it might not
7 render him all the way unconscious. But even their own
8 expert said, I don't know. I can't say. It's sheer
9 speculation at that point.

10 Moreover, Virginia, as Mr. Robinson testified, has
11 precautions built in to its protocol, its lethal injection
12 protocol, that if the inmate has not been rendered
13 unconscious, we'll know about it before we go forward with
14 the execution. That greatly minimizes any risk of even
15 the slightest amount of pain in the event that perhaps the
16 pentobarbital is not as completely efficacious as
17 Mr. Prieto might like for it to be.

18 The possibilities and speculative scenarios, the
19 parade of horrors that are listed in the plaintiff's
20 pleading, are sufficient -- are just insufficient to rise
21 to the level of an Eighth Amendment violation.

22 With regard to Virginia was entitled to rely upon
23 Texas, there's a presumption of regularity that attaches
24 to officials in the course of their official duties. To
25 the extent that the allegations that Virginia acted

1 unreasonable, I don't think that's borne out by the
2 circumstances at all.

3 Mr. Robinson said, you know, if they had said that
4 they refused to provide us any information, if they had
5 refused to verify that this was what it claims to be, we
6 would not have taken it. They acted reasonably under all
7 of the circumstances.

8 As Your Honor mentioned before, I don't believe
9 there's been any showing of an available alternative, and
10 so that's the second prong of the *Glossip* test that's not
11 been satisfied under these circumstances either.

12 So, in sum, there's no likelihood of success on the
13 merits here. Preliminary injunctive relief should not be
14 issued.

15 I'll touch briefly, briefly on the other remaining
16 elements for injunctive relief. With respect to
17 irreparable harm, this Court stated in *Reid*, there is
18 simply no reason to believe that the speculative list of
19 horrors described by the inmate are likely to come to
20 pass. The likelihood of the inmate suffering irreparable
21 harm from the manner in which the defendant intends to
22 carry out the sentence is so remote as to be nonexistent.

23 And that is precisely the scenario before the Court
24 today.

25 The balance of the equities, counsel referenced the

1 fact that Mr. Prieto apparently sent a letter. I don't
2 believe that any of that is in evidence or attached to any
3 of the pleadings. I'm not familiar with any of that. The
4 Department of Corrections couldn't give a certificate of
5 analysis that they didn't have. We have it.

6 The balance of the equities also weigh in favor of
7 denying equitable relief because, as they made a big deal
8 of, a drug's potency is decreased over time. If we were
9 to delay his execution at this juncture, Virginia's
10 ability to execute this serial murder rapist would
11 diminish. The balance of the equities tend in favor of
12 proceeding with the execution, particularly in light of
13 the highly speculative nature of the pleadings and the
14 allegations before the Court.

15 Filing a 1983 suit does not entitle you to a stay of
16 your execution. You are not entitled to a stay just to
17 get discovery in the case.

18 As the Eighth Circuit stated in the *Zink* case, they
19 rejected his argument that I need a stay to find out if
20 more information exists. The grounds of Eighth Amendment
21 claims should not be permitted to achieve indirectly a
22 defacto injunction against a lawful method of execution.
23 That's precisely what we have here.

24 Finally, there is a public interest here in finally
25 bringing closure to the many victims of Mr. Prieto.

1 A quote from the *Thompson* case, 523 U.S. 538. "*When*
2 *lengthy federal proceedings have run their course and a*
3 *mandate denying relief has issued, finality acquires an*
4 *added moral dimension. Only with an assurance of real*
5 *finality can the State execute its moral judgment in a*
6 *case. Only with real finality can the victims of crime*
7 *move forward knowing the moral judgment will be carried*
8 *out.*"

9 To unsettle these expectations is to inflict, to
10 inflict, a profound injury to the powerful, a legitimate
11 interest in punishing the guilty, an interest shared by
12 the state and victims of crimes alike.

13 It has been 27 years since the bodies of two 22-year
14 old children, children basically, graduate students, were
15 found in that cold field in Fairfax. Twenty-seven years
16 since the family and acquaintances of Warren Fulton and
17 Rachael Ranever, some of whom are in the courtroom today,
18 27 years since they were told that Rachael had been shot
19 and raped as she lay dying. Twenty-seven years since
20 Warren was shot in the back.

21 It is time for this to stop now. It is time for the
22 carousel to end. It is time for justice to be brought for
23 them. It is time to end all of this, and let Mr. Prieto's
24 execution proceed and commence.

25 I ask the Court to vacate the TRO, and to dismiss the

1 preliminary injunction.

2 THE COURT: Ms. O'Shea, thank you very much.

3 Mr. Lee, I'll give you the final word, sir.

4 MR. LEE: I believe the evidence presented shows that
5 there was no sterility testing done on these drugs. It
6 also shows that the drugs were kept at room temperature
7 apparently before they were received, as Ms. O'Shea just
8 said, during transport, and since. And the science shows
9 that compounded pentobarbital kept at room temperature has
10 a beyond use date of 24 hours. The drugs were
11 manufactured -- excuse me, prepared in April of 2015. I
12 believe the evidence conclusively shows that these drugs
13 are not scientifically usable -- or science shows that
14 they should not be used.

15 THE COURT: Mr. Lee, I wasn't going to bring this up
16 until you teed the point up. One thing that was
17 conspicuously absent in your evidence -- and I thought
18 Dr. Ruble was a very impressive pharmacologist. No
19 question about it. But when you asked him questions about
20 whether or not these standards apply to an execution, he
21 dodged the questions. He never once said that he had any
22 experience whatever, and there's not a shred of evidence
23 that the same standards would apply in an execution
24 setting. And when the question was asked of him, he very
25 gingerly dodged it.

1 MR. LEE: Well, Your Honor, I'll just say that the
2 very drugs they have that they obtained have a beyond use
3 date on them. Published on them. And the beyond use
4 date --

5 THE COURT: April 14, 2016. What's today? Today is
6 October 1, 2015.

7 MR. LEE: Yeah. Exactly, Your Honor.

8 But if you look -- I encourage you to look at The
9 United States Pharmacopeia. That's the science of the
10 drugs. And the drugs that are going to be used, are going
11 to be used far outside anything that science will allow.

12 THE COURT: All right, sir. Thank you very much.

13 All right. I appreciate this very much. Counsel did
14 a superb job in the time frame you had here. I appreciate
15 it very much.

16 I will stand in recess at this point. An opinion
17 will be issued today.

18 MR. LEE: Thank you, Your Honor.

19 (The proceeding concluded at 3:12 p.m.)

20 REPORTER'S CERTIFICATE

21 I, Krista Liscio Harding, OCR, RMR,
Notary Public in and for the Commonwealth of
22 Virginia at large, and whose commission expires
March 31, 2016, Notary Registration Number 149462,
do hereby certify that the pages contained herein
23 accurately reflect the notes taken by me, to the
best of my ability, in the above-styled action.
Given under my hand this 13th day of November, 2015.

24 _____
25 Krista Liscio Harding, RMR
Official Court Reporter